An Evaluation of Sexual Functioning in Employed Outpatients with Major Depressive Disorder Treated with Desvenlafaxine 50 mg or Placebo

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ABSTRACT

Introduction. The symptoms of major depressive disorder (MDD) include sexual dysfunction, but antidepressant pharmacotherapies are also associated with treatment-emergent sexual dysfunction.

Aim. These secondary and post hoc analyses evaluated sexual functioning in employed adult outpatients with MDD treated with desvenlafaxine (administered as desvenlafaxine succinate) and placebo.

Method. Patients were randomly assigned (2:1 ratio) to 12 weeks of double-blind treatment with desvenlafaxine 50 mg/day or placebo.

Main Outcome Measures. The Arizona Sexual Experiences Scale (ASEX) was administered every 4 weeks. Analysis of covariance was used to compare differences in mean change from baseline ASEX scores between desvenlafaxine and placebo for women and men.

Results. There were 422 evaluable patients with baseline ASEX scores (desvenlafaxine, N = 281; placebo, N = 141). Among women (desvenlafaxine, N = 184; placebo, N = 92), baseline scores were 20.0 (5.2) and 20.5 (5.3) for desvenlafaxine and placebo, respectively; mean changes at week 12 were −1.93 (0.37) and −1.03 (0.54), respectively (mean difference: 0.90 [−0.38, 2.18]; P = 0.169). Among men (desvenlafaxine, N = 97; placebo, N = 49), baseline scores were 16.4 (4.9) and 15.9 (4.8) for desvenlafaxine and placebo, respectively; mean changes at week 12 were −1.13 (0.47) and −1.06 (0.70), respectively (mean difference: 0.07 [−1.59, 1.74]; P = 0.932). Significantly greater orgasmic dysfunction at week 12 was observed in the subgroup of men without baseline sexual dysfunction treated with desvenlafaxine relative to placebo. Conversely, women without baseline sexual dysfunction experienced poorer overall sexual functioning and orgasm satisfaction at week 12 with placebo relative to desvenlafaxine treatment. Subgroup analyses of treatment responders and nonresponders found no difference in the proportion of men or women that developed or had resolution of sexual dysfunction in the desvenlafaxine and placebo groups.

Conclusion. With the exception of orgasmic dysfunction in men without preexisting sexual dysfunction, no significant negative effect on sexual functioning was observed over 12 weeks of treatment with desvenlafaxine. Clayton AH, Reddy S, Focht K, Musgnung J, and Fayyad R. An evaluation of sexual functioning in employed outpatients with major depressive disorder treated with desvenlafaxine 50 mg or placebo. J Sex Med 2013;10:768–776.

Key Words. Antidepressant; Desvenlafaxine; Sexual Functioning
antidepressant. The prevalence of antidepressant treatment-emergent sexual dysfunction from a number of studies ranged from 18% to 82% depending on the specific drug and phases of the sexual response cycle affected [4–6]. It has been suggested that ejaculatory and orgasmic dysfunction or decreases in physiological arousal (i.e., erectile dysfunction in men and a lack of vaginal lubrication in women) are most commonly associated with antidepressant use, while the sexual dysfunction that is part of the depressive disease state is more likely to manifest as decreased sexual desire or overall satisfaction [2,3]. However, in a population of antidepressant-free patients with MDD, 40% to 50% of men and women reported decreased sexual desire and reduced arousal, while 15% to 20% reported ejaculatory or orgasmic difficulties [3].

Numerous endocrine factors, neurotransmitters, and neuropeptides are involved in the human sexual response cycle. For example, noradrenergic-noradrenergic innervations are responsible for initiating the male erectile process by relaxing the smooth muscles that allow blood flow to the penis. Serotonin activity has a negative effect on sexual functioning particularly in the processes involving vasodilatation and vasoconstriction, and norepinephrine has positive effects on arousal, and on dopamine function [7,8].

The primary neurobiological correlate of the sexual dysfunction observed in antidepressant-treated patients is thought to be serotonin-2 receptor activation, but a variety of other factors, such as nitric oxide function and prolactin levels may also play a role. Therefore, the dysregulation of serotonergic and noradrenergic activity that has also been linked to MDD [9] may help explain the symptoms of sexual dysfunction that are associated with the depressive disease state.

Aim

Using data collected from a study designed to assess the efficacy of desvenlafaxine 50 mg/day (administered as desvenlafaxine succinate) for improving depressive symptoms and functioning in a population of employed outpatients with depression [10], we evaluated sexual functioning measured prospectively throughout the study using the validated, patient-rated Arizona Sexual Experiences Scale (ASEX) [11]. Assessment of changes in sexual functioning on the ASEX was an a priori secondary end point of the study.

The primary results of the study were previously reported [10] and demonstrated the effectiveness of desvenlafaxine for decreasing depressive symptom severity, improving functioning, and decreasing disability. The ASEX data were chosen for separate presentation to allow for further exploration and discussion of the results. The objectives of the current analysis were to examine the effect of desvenlafaxine treatment on sexual functioning in men and women; to assess positive or negative changes in sexual functioning over the 12-week study period stratified by the presence or absence of pretreatment sexual dysfunction; and to explore the relationship between treatment response and the emergence or resolution of sexual dysfunction.

Methods

Study Design

Details regarding the design of the primary study and the patient population have been reported elsewhere [10]. In summary, the study was a phase 3b, multisite, 12-week, randomized, double-blind, placebo-controlled clinical trial that assessed the efficacy of desvenlafaxine for improving depressive symptoms and functional impairment. Eligible patients were required to have a primary diagnosis of MDD with a duration of current depressive episode ≥30 days and a Montgomery-Asberg Depression Rating Scale [12] total score ≥25 at both screening and baseline visits. Gainful employment was defined as working ≥20 paid hours per week, and pretreatment functional impairment was defined as a baseline Sheehan Disability Scale (SDS) [13] score ≥10. Patients were randomly assigned (2:1 ratio) to receive 12 weeks of treatment with desvenlafaxine 50 mg/day or a matching placebo. The primary depression outcome measure was the 17-item Hamilton Rating Scale for Depression (HAM-D17) [14], and the key secondary outcome selected to assess disability was the SDS, which measured the patient’s level of functioning in his or her work or school, family, and social roles.

Main Outcome Measure

These analyses assessed the impact of 12 weeks of treatment with desvenlafaxine 50 mg and placebo on sexual functioning, defined as change from baseline ASEX total scores. The ASEX is a five-item assessment of sexual functioning that uses gender-specific language to measure the patient’s...
sex drive, ease of both psychological and physiological arousal, and ease of and satisfaction with orgasm. The five questions include (i) “How strong is your sex drive?”; (ii) “How easily are you sexually aroused (turned on)?”; (iii) “Can you easily get and keep an erection?” (ASEX-Male) or “How easily does your vagina become moist or wet during sex?” (ASEX-Female); (iv) “How easily can you reach an orgasm?”; and (v) “Are your orgasms satisfying?”. For each item patients are asked to indicate their overall experience during the past week (including the day of assessment), with responses measured on a Likert scale of 1 to 6 with an item score of 1 or 2 indicating hyperfunction (little or no impairment) while a score of 5 or 6 indicates hypofunction (severe or complete impairment) [11]. ASEX assessments were conducted at baseline and the weeks 4, 8, and 12 visits or, in cases of early withdrawal, at the patient’s final visit.

An observed cases (OC) analysis was conducted of mean change from baseline ASEX total scores between the desvenlafaxine 50 mg and placebo groups. Because the ASEX questions are gender specific with different questions for men and women, ASEX total scores were analyzed separately by gender. These analyses were a priori secondary outcomes in the original, previously referenced study [10]. Post hoc analyses included week 12 ASEX scores analyzed by the presence of baseline sexual dysfunction to determine whether positive or negative changes in sexual functioning over the 12-week study period were influenced by the presence or absence of disease state sexual dysfunction. Sexual dysfunction was defined as a baseline ASEX total score ≥19 or a score ≥5 on any single item or scores ≥4 on any three individual items [11]. Decreases in ASEX scores represent improvements in sexual functioning. In addition, the presence of week 12 sexual dysfunction was analyzed by week 12 depression treatment response status (defined as a ≥50% change from baseline on the HAM-D17) to explore the relationship between treatment response and the emergence or resolution of sexual dysfunction.

Statistical Analyses
The evaluable population for this analysis included all randomly assigned patients who took at least one dose of study medication and had a baseline ASEX evaluation. All analyses were performed using OC data. Differences in between-group change from baseline scores for subjects with and without baseline sexual dysfunction were assessed using analysis of covariance (ANCOVA) with baseline score and treatment group as covariates. To examine consistency of treatment effect across subjects with and without sexual dysfunction, treatment-by-sexual dysfunction was tested at the 0.1 significance level using an ANCOVA model with treatment, baseline, presence or absence of sexual dysfunction, and treatment-by-sexual dysfunction interaction. The proportion of subjects with emergence or resolution of sexual dysfunction was compared between treatments using the Fisher’s exact test.

Results
Figure 1 shows the number of patients and gender distribution in each of the subgroups analyzed. The evaluable analysis population (defined as those who took at least one dose of study medication and had a baseline ASEX evaluation) included 422 patients. As expected in a population of depressed patients, the majority of the sample was female (65.4% women). The mean (standard deviation) age of female patients enrolled in this study was 41.7 (12.1) years; the mean age of male patients was 44.1 (11.6) years.

ASEX Total Score
Baseline total ASEX score was 20.0 and 20.5 for female patients taking desvenlafaxine and placebo, respectively, and 16.4 and 15.9 for male patients taking desvenlafaxine and placebo, respectively. At week 12, neither female (mean difference: 0.90 [–0.38, 2.18]; P = 0.169) nor male (mean difference: 0.07 [–1.59, 1.74]; P = 0.932) patients that were treated with desvenlafaxine experienced significantly different changes in sexual functioning compared with patients treated with placebo (Figure 2).

Baseline Sexual Dysfunction Analysis
At baseline, 78.6% (217/276) of women and 46.6% of men (68/146) met ASEX criteria for sexual dysfunction. The presence of baseline sexual dysfunction did not have a significant effect on the differences between the desvenlafaxine 50-mg and placebo groups in male (Table 1) or female (Table 2) patients for the ASEX total score. However, male patients that were not experiencing sexual dysfunction at baseline and were being treated with desvenlafaxine had significantly higher week 12 scores (decreased sexual functioning) on the “How easily can you reach an orgasm?” item compared with the placebo group.
Treatment-by-sexual-dysfunction interaction was significant at the 0.1 level \( (P = 0.059) \) for this item indicating that treatment effect was not consistent across the sexual dysfunction categories. The tests for interaction for the other items in men were not significant. In contrast to the findings in men, female patients without preexisting sexual dysfunction who were treated with placebo had significantly poorer week 12 outcomes compared with desvenlafaxine on ASEX total score (mean difference: 2.9 [0.17, 5.59]; \( P = 0.038 \)) and on the “Are your orgasms satisfying?” item (mean difference: 0.6 [0.1, 1.2]; \( P = 0.035 \)). The treatment-by-sexual-dysfunction interaction for these items in women was not significant.

Figure 1 Analysis subgroup diagram. The evaluable analysis population included all randomized patients who took at least one dose of study medication and had a baseline Arizona Sexual Experiences Scale evaluation. Full details of the study population including number of patients screened, enrolled, and randomized were previously published in Dunlop et al. [10]. OC = observed cases.
Resolution of Sexual Dysfunction

The proportion of male and female patients who experienced resolution of their baseline sexual dysfunction (i.e., those who crossed the threshold from having sexual dysfunction at baseline to not having sexual dysfunction after 12 weeks of treatment) are presented in Figure 3.

In the total population of female patients (Figure 3A) with baseline sexual dysfunction, 34% of desvenlafaxine-treated women and 25% of

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Table 1  Total and individual ASEX item scores in male patients with and without baseline sexual dysfunction (observed cases)

<table>
<thead>
<tr>
<th></th>
<th>Baseline sexual dysfunction (N = 68)</th>
<th>No baseline sexual dysfunction (N = 78)</th>
<th>Treatment-by-sexual-dysfunction interaction, P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline mean (SD)</td>
<td>Week 12 mean (SE)</td>
<td>Difference (95% CI); P value</td>
</tr>
<tr>
<td>ASEX total</td>
<td>Desvenlafaxine 50 mg</td>
<td>19.9 (3.6)</td>
<td>17.6 (0.7)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>21.2 (2.5)</td>
<td>18.9 (1.2)</td>
</tr>
<tr>
<td>How strong is your sex drive?</td>
<td>Desvenlafaxine 50 mg</td>
<td>4.6 (1.1)</td>
<td>3.6 (0.2)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>4.9 (0.8)</td>
<td>4.1 (0.3)</td>
</tr>
<tr>
<td>How easily are you sexually aroused?</td>
<td>Desvenlafaxine 50 mg</td>
<td>4.1 (1.0)</td>
<td>3.5 (0.2)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>4.4 (0.7)</td>
<td>3.9 (0.3)</td>
</tr>
<tr>
<td>Can you easily get and keep an erection?</td>
<td>Desvenlafaxine 50 mg</td>
<td>3.9 (1.2)</td>
<td>3.4 (0.2)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>4.2 (0.8)</td>
<td>3.8 (0.3)</td>
</tr>
<tr>
<td>How easily can you reach an orgasm?</td>
<td>Desvenlafaxine 50 mg</td>
<td>3.9 (1.1)</td>
<td>3.7 (0.1)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>4.0 (1.0)</td>
<td>3.8 (0.2)</td>
</tr>
<tr>
<td>Are your orgasms satisfying?</td>
<td>Desvenlafaxine 50 mg</td>
<td>3.5 (1.3)</td>
<td>3.3 (0.2)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>3.7 (0.9)</td>
<td>3.5 (0.3)</td>
</tr>
</tbody>
</table>

*Significant at 0.1

ASEX = Arizona Sexual Experiences Scale; SD = standard deviation; SE = standard error; CI = confidence interval

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Table 2  Total and individual ASEX item scores in female patients with and without baseline sexual dysfunction (observed cases)

<table>
<thead>
<tr>
<th></th>
<th>Baseline sexual dysfunction (N = 217)</th>
<th>No Baseline sexual dysfunction (N = 59)</th>
<th>Treatment-by-sexual-dysfunction interaction, P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline mean (SD)</td>
<td>Week 12 mean (SE)</td>
<td>Difference (95% CI); P value</td>
</tr>
<tr>
<td>ASEX total</td>
<td>Desvenlafaxine 50 mg</td>
<td>21.9 (4.4)</td>
<td>19.6 (0.4)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>22.1 (4.4)</td>
<td>20.1 (0.6)</td>
</tr>
<tr>
<td>How strong is your sex drive?</td>
<td>Desvenlafaxine 50 mg</td>
<td>5.1 (0.8)</td>
<td>4.4 (0.1)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>5.1 (1.1)</td>
<td>4.5 (0.2)</td>
</tr>
<tr>
<td>How easily are you sexually aroused?</td>
<td>Desvenlafaxine 50 mg</td>
<td>4.6 (1.0)</td>
<td>4.0 (0.1)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>4.5 (1.0)</td>
<td>4.2 (0.1)</td>
</tr>
<tr>
<td>How easily does your vagina become moist?</td>
<td>Desvenlafaxine 50 mg</td>
<td>4.0 (1.3)</td>
<td>3.7 (0.1)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>4.1 (1.4)</td>
<td>3.8 (0.1)</td>
</tr>
<tr>
<td>How easily can you reach an orgasm?</td>
<td>Desvenlafaxine 50 mg</td>
<td>4.5 (1.1)</td>
<td>4.1 (0.1)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>4.7 (1.0)</td>
<td>4.2 (0.1)</td>
</tr>
<tr>
<td>Are your orgasms satisfying?</td>
<td>Desvenlafaxine 50 mg</td>
<td>3.7 (1.4)</td>
<td>3.5 (0.1)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>3.8 (1.6)</td>
<td>3.7 (0.2)</td>
</tr>
</tbody>
</table>

ASEX = Arizona Sexual Experiences Scale; SD = standard deviation; SE = standard error; CI = confidence interval
placebo-treated women no longer had sexual dysfunction at week 12; this difference was not statistically significant ($P = 0.312$). In the subgroups of female patients with and without an antidepressant response to treatment, the percentage of patients who no longer had sexual dysfunction at week 12 were not significantly different between treatment groups.

In the total population of male patients (Figure 3B), 50% of the desvenlafaxine group had resolution of their baseline sexual dysfunction at week 12 compared with 31% of the placebo group (nonsignificant; $P = 0.343$). Among male patients with sexual dysfunction at baseline who responded to treatment, the percentage who did not have sexual dysfunction at week 12 was twofold greater for desvenlafaxine compared with placebo (54% vs. 25%, respectively); this difference was not statistically significant ($P = 0.236$). For male patients with baseline sexual dysfunction, who did not respond to treatment, the percentage not experiencing week 12 sexual dysfunction was 44% and 40% for the desvenlafaxine and placebo groups, respectively.

**Emergence of Sexual Dysfunction**

The proportion of male and female patients that developed treatment-emergent sexual dysfunction (i.e., those who did not meet the criteria for sexual dysfunction at baseline but met these criteria at week 12) are presented in Figure 4.

For all female patients (Figure 4A), there was a trend toward a lower rate of emergent sexual dysfunction over the 12 weeks of treatment in the desvenlafaxine group (11%) compared with the placebo group (36%) ($P = 0.063$). Similar rates were observed when analyzing these data by female responder status; however, the differences in the subgroups of responders and nonresponders were not statistically significant ($P = 0.195$ and 0.506, respectively).

For male patients (Figure 4B), the proportion of the desvenlafaxine group that developed sexual dysfunction at week 12 was not significantly different from placebo ($P = 0.696$). When analyzing these data by responder status, comparable rates of emergent sexual dysfunction were observed in responders to desvenlafaxine and placebo (14.8% vs. 14.3%, respectively), while in nonresponders, 9.1% of desvenlafaxine-treated patients developed sexual dysfunction compared with no placebo patients. This difference was not significant. These results should be viewed with caution as the populations were very small, particularly in the nonresponders (1/11 in the desvenlafaxine and 0/10 in the placebo group developed sexual dysfunction at week 12).

**Discussion**

The main objective of these analyses was to compare the effects of 12 weeks of desvenlafaxine
50 mg treatment vs. placebo on overall sexual functioning in a population of gainfully employed, depressed outpatients. The results revealed that overall sexual functioning as measured by ASEX total scores in male and female patients taking desvenlafaxine 50 mg/day was similar to patients taking placebo. It is possible that drug-related negative effects could be partially offset by the greater treatment response with desvenlafaxine compared with placebo, which could be followed by subsequent improvement in sexual dysfunction as the depression symptoms resolve. However, results in the nonresponders were similar in both treatment groups (desvenlafaxine and placebo) for males and females, also suggesting the absence of a negative effect of desvenlafaxine on overall sexual functioning.

Despite the lack of differences in overall functioning, we did observe some differences between the treatment groups in individual domains of sexual functioning. An increase in orgasmic dysfunction at week 12 was observed with desvenlafaxine compared with placebo patients in the subgroup of men who did not meet the criteria for baseline sexual dysfunction. This result may suggest the development of sexual dysfunction in this population. Interestingly, after 12 weeks of treatment, women without baseline sexual dysfunction who received placebo had both a significant worsening in overall sexual functioning and had less satisfactory orgasms when compared with similar females that were treated with desvenlafaxine. These findings may suggest the development or worsening of disease state sexual dysfunction associated with MDD among patients treated with an inactive or ineffective agent.

Previously reported results from an integrated safety analysis of nine clinical trials that assessed the safety and efficacy of desvenlafaxine 50 to 400 mg demonstrated that the most commonly reported sexual side effect was erectile dysfunction in males as recorded by spontaneously reported treatment-emergent adverse events. In the desvenlafaxine 50 mg group, 3% of male patients reported erectile dysfunction compared with 1% of the placebo group [15]. The current study identified a worsening in male patients without preexisting sexual dysfunction who were treated with desvenlafaxine based on the question “How easily can you reach orgasm?” but no differences were observed on the ASEX item related to erectile dysfunction (“How easily can you get and keep an erection?”). This difference may be due to differences in terminology between the ASEX and the adverse event coding system used in the integrated safety analysis. In addition, because the adverse events in the integrated analysis were spontaneously reported, the rates may be lower than those observed using the methods in the present study, which used a structured rating scale (i.e., the ASEX), as has been observed previously [16].

Other clinical trials have demonstrated sexual dysfunction as an adverse event for antidepressants...
that work as serotonin-norepinephrine reuptake inhibitors (i.e., drugs that work via the same mechanism as desvenlafaxine) [17,18]. A comparison of the occurrence of treatment-emergent sexual dysfunction following treatment with duloxetine 40–120 mg/day, paroxetine 20 mg/day, or placebo using the same structured questionnaire in the current study demonstrated that among patients that did not meet criteria for sexual dysfunction at baseline (ASEX ≥5 on any individual ASEX item), both antidepressants were associated with higher rates of sexual dysfunction at end point relative to placebo. Those treated with paroxetine were significantly more likely to meet criteria for sexual dysfunction at end point (61.4%) compared with those treated with duloxetine (46.4%; \(P < 0.05\) vs. paroxetine) or placebo (28.8%; \(P < 0.001\) vs. paroxetine; \(P < 0.01\) vs. duloxetine). Similar results were observed when analyzed by gender; however, only male patients treated with paroxetine had rates of sexual dysfunction that were significantly higher than the placebo group. Conversely, no significant differences in the proportion of patients with resolution of baseline sexual dysfunction were observed: duloxetine, 34.9%; paroxetine, 36.1%; placebo, 29.9% [17]. Variations between the definitions of sexual dysfunction used in the current study and the analysis conducted by Delgado and colleagues [17] and the different patient populations may account for the broad differences in the rates of treatment-emergent sexual dysfunction that were observed between the two.

A number of limitations of these analyses require mentioning. ASEX data are self-reported, and the threshold score is derived from face validity. The ASEX may have missed other sexual dysfunctions or contributing factors not captured by the ASEX, and since a comparator agent was not included in the study, the sensitivity of the ASEX in this trial to find a difference if one exists is not known. The absence of statistically significant differences between desvenlafaxine and placebo, particularly in the subgroups that were evaluated, must be considered preliminary. Although the ASEX analysis was part of the a priori statistical plan, the study was not specifically powered to evaluate changes in sexual functioning. The largest subgroup evaluated was female patients with baseline sexual dysfunction, which accounted for slightly more than half of the total patient population. This relative proportion is consistent with what would be seen in clinical practice; however, the smaller number of patients in the other subgroups, particularly male patients with and without baseline sexual dysfunction, makes it difficult to definitively determine the presence or absence of a true pharmacologic effect of the drug in these small populations.

As the duration of this study was 12 weeks, it is not possible to evaluate changes in sexual functioning over a longer period of treatment. However, clinical trials with desvenlafaxine have identified sexual dysfunction in treatment periods as short as 8 weeks [15], and a global negative effect of a selective serotonin reuptake inhibitor on sexual function in normal controls was clearly evident using the Changes in Sexual Functioning Questionnaire within 2 weeks of drug initiation [19]. A study by Montejo and colleagues [20] of sexual dysfunction during longer-term treatment (1 year and beyond) with duloxetine found a relatively low probability of newly emergent treatment-related sexual dysfunction among those who responded and were stable on antidepressant treatment. Continued or emergent sexual dysfunction was influenced to a greater extent by the depression status of the patient (i.e., recurrence vs. continued response) than the treatment itself. Thus, 12 weeks appears to be an adequate time period to determine acute treatment sexual functioning side effects, with further effects on sexual functioning unlikely unless depressive symptoms recur.

Conclusions

Despite the limitations described above, these data suggest that with the exception of increased orgasmic dysfunction in men without preexisting sexual dysfunction, the effects of desvenlafaxine on sexual functioning were comparable to placebo over 12 weeks of treatment. Placebo-treated women without sexual dysfunction at baseline experienced significant worsening in overall sexual functioning and less satisfactory orgasms at end point, which may represent disease state sexual dysfunction related to not receiving an active treatment for depression. The results from these secondary analyses should be viewed cautiously due to the small populations in some of the subgroups of interest; however, they may provide directions for future research.

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Pfizer, Inc, Repligen Corporation and Takeda Pharma. She has participated on advisory boards and received consulting fees from Astellas Pharma US, Inc., Bayer, Boehringer-Ingelheim, Dey Pharma, DP, Eli Lilly & Co., Euthymins, Forest Pharma, GlaxoSmithKline, New England Research Institutes, NovaDel, Palatin Technologies, Pfizer Inc, Sunovion Pharmaceuticals, Inc and Takeda Global Research & Development. She also receives royalties from the Changes in Sexual Functioning Questionnaire; Guilford Publications; and Healthcare Technology Systems, Inc. Sujana Reddy, Kristen Focht, Jeff Musgnung, and Rana Fayyad are full-time Pfizer employees.

Statement of Authorship

Category 1
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(b) Acquisition of Data
Anita H. Clayton; Kristen Focht; Jeff Musgnung
(c) Analysis and Interpretation of Data
Rana Fayyad; Anita H. Clayton; Kristen Focht; Jeff Musgnung; Sujana Reddy

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(b) Revising It for Intellectual Content
Anita H. Clayton; Kristen Focht; Jeff Musgnung; Rana Fayyad; Sujana Reddy

Category 3
(a) Final Approval of the Completed Article
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References