Sexual Function in Postpartum Women Treated for Depression: Results From a Randomized Trial of Nortriptyline Versus Sertraline

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Objective: The primary aim of this article is to describe sexual concerns in postpartum women with DSM-IV diagnoses of major depressive disorder (MDD) before and during treatment with antidepressants in an 8-week double-blind randomized trial.

Method: Seventy women aged 19–42 years participated and were randomly assigned to either the tricyclic antidepressant nortriptyline (N = 38) or the serotonin selective reuptake inhibitor sertraline (N = 32). Women completed the Arizona Sexual Experience Scale to evaluate sexual concerns at enrollment and weekly during the trial. The outcome measure for depression, Hamilton Rating Scale for Depression, was completed in clinical interviews at the same time points. Comparisons of demographic and other characteristics of women were completed with t tests for continuous measures and with χ^2 or Fisher exact statistics for categorical measures. Mixed-effects regressions were used to test for significance of the main effects of depression symptom scores, drug assignment, weeks treated with medication, and the interactions of these variables. Data were collected from April 1997 to April 2002.

Results: At entry into the randomized trial, 73% (N = 51) of the women reported problems in 3 or more areas of sexual concern compared to 37% (N = 26) at week 8. There were no significant differences at study entry in women randomly assigned to nortriptyline compared to those randomly assigned to sertraline in summary scores of sexual function nor in specific sexual concerns at any time point. At week 8, women whose MDD remitted were more likely to report fewer (< 3) sexual concerns than women whose MDD did not remit (76% vs. 24%, p = .006), independent of drug assignment.

Conclusions: In postpartum women, sexual concerns are primarily affected by remission of depression rather than side effects of either a tricyclic or serotonergic antidepressant.

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Sexual health concerns are common after childbirth. A recent review of the literature has shown that up to 53% of women reported sexual problems in the first 3 months postpartum, and up to 49% at 6 months after delivery.[1] Within the first 3 months after giving birth, 80% to 93% of women resumed sexual activities; however, problems such as dyspareunia and decreased libido were commonly reported. These concerns declined at 6 months and resolved across the first postpartum year.[2–4] Factors related to sexual concerns in the puerperium include breastfeeding,[5] obstetric morbidity,[6] perineal trauma sustained at delivery,[7] and psychosocial changes, such as role transition, changes in body image, and adjustment in marital satisfaction and relationships.[8]

Sexual problems are also related to psychiatric conditions such as major depression. Decreased libido has been reported in up to 50% of drug-free men and women with major depressive disorder (MDD)[9–11] and in over 50% in some studies.[12,13] Comparative studies show that the prevalence of sexual dysfunction in depressed patients is greater than in normal controls.[10,12] Depression produces difficulties in intimacy through psychological (global decrease in pleasure and interest, lowered self-esteem, social withdrawal) and physical (e.g., effects of the

neurotransmitters dopamine and serotonin on hormonal functioning) mechanisms.

Sexual dysfunction is also frequently encountered as a treatment-emergent side effect associated with antidepressant therapy that has a detrimental effect on quality of life and adherence to treatment. The prevalence of antidepressant-induced sexual dysfunction in France and the United Kingdom was reported as high as 26.6% and 39.2%, respectively.[14] In a survey of 3516 members of patient advocate groups, sexual dysfunction was among the most commonly identified side effects leading to treatment dropout.[15] The incidence of sexual side effects differs according to the pharmacologic profile of medications used. Antidepressants with predominantly serotonergic effects have generally been associated with the highest incidence.[16–20] While in the general population the prevalence of sexual dysfunctions is higher in women compared to men,[21] the opposite occurs among depressed patients undergoing treatment with antidepressants.[22,23] The hesitancy of patients to report adverse events related to sexual function leads to a pronounced underestimation of such events in clinical trials.[22,24] The prevalence of selective serotonin reuptake inhibitor (SSRI)-induced sexual dysfunction has been estimated as high as 58% when identified by physician questioning compared to 14% when spontaneously reported.[22] Similarly, in a study of patients with refractory depression, sexual dysfunction occurred in 41% of patients when directly assessed compared to 6% when assessed by spontaneous reports.[25]

Obtaining accurate data on sexual functioning is particularly challenging among postpartum women. Barrett et al.[3] reported that only 15% of women discussed sexual problems with their health care professional. After childbirth, women are reluctant to approach health professionals but appreciate the opportunity to discuss their problems if the physician initiates the conversation.[5] The majority of the new mothers are reluctant to discuss sexual health concerns because conditions related to the childbirth are regarded by mothers as somewhat of a taboo.[26,27] As a consequence, women are not provided with information on sexual function in the postpartum period. To date, no investigations of the incidence of sexual concerns in postpartum depressed women or the relationship of these concerns with treatment response or class of antidepressant medication have been published.

The primary aims of this article were to describe the frequency of sexual concerns in depressed postpartum women, evaluate the impact of efficacious antidepressant medication treatment on sexual function, and compare the sexual concerns of women treated with nortriptyline versus sertraline over an 8-week period. We hypothesized the following: (1) Postpartum women with high depression symptom scores would report high levels of sexual concerns and low levels of sexual function. (2) Successful treatment of postpartum depressed women would be associated with fewer sexual concerns and improved sexual functioning at 8 weeks. (3) Improvement in sexual function would be greater in nortriptyline-treated compared to sertraline-treated women due to the sexual side effects of serotonergic medications. An exploratory aim was to compare the individual items on the Arizona Sexual Experience Scale (ASEX) for improvement related to remission or nonremission of postpartum MDD.

METHOD

Design

The parent study from which these data were derived was a double-blind, acute-phase, 8-week randomized clinical trial (nortriptyline vs. sertraline for postpartum depression), which has been described in detail elsewhere.[28] Data for this analysis were derived from subjects at 2 of the 3 sites in the parent study: Cleveland, Ohio (N = 65), and Louisville, Kentucky (N = 5). The institutional review boards approved the protocol, and after complete description of the study to the subjects, written informed consent was obtained. This report focuses on the subjects' self reports of sexual function collected as part of the original study.[28] Dates in which data were collected were as follows: Cleveland, Ohio (April 1997 to April 2000), and Louisville, Kentucky (December 2001 to April 2002). The principal investigator moved to the University of Pittsburgh in 2002.

Subjects aged 15 to 45 years with MDD with postpartum onset (within 4 weeks of birth according to American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition) were eligible. Mothers had to present for treatment within 3 months of delivery. A 17-item Hamilton Rating Scale for Depression (HAM-D)[29] score of 18 or more was required for inclusion. Exclusion criteria were the presence of any other Axis I disorder except generalized anxiety disorder or panic disorder, contraindications to tricyclic antidepressant treatment, and concurrent psychiatric treatment. The primary outcomes for depression from the original study were response at 8 weeks (50% reduction in HAM-D score from baseline to week 8) and remission (HAM-D score ≤ 7).

Subjects were randomly assigned 1:1 to either nortriptyline or sertraline. All subjects were treated with a fixed-dose strategy. Doses were not titrated to serum level as is usually done for nortriptyline because therapeutic levels for sertraline have not been defined, and this approach would offer an advantage to nortriptyline. The dosing began with 25 mg/day of sertraline or 10 mg/day of nortriptyline. Thereafter, the doses were increased to 50 mg/day of sertraline and 25 mg/day of nortriptyline and increased until either response or side effects prohibited further dose escalation. The maximum doses were 200 mg/day of sertraline and 150 mg/day of nortriptyline. At 8 weeks,

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Table 1. Baseline Characteristics of Women With Postpartum MDD According to Remission Status and Drug Assignment

	Remission Status at 8 Weeks[a]				Drug Assignment			
	Nonremitter	Remitter	Statistics		Nortriptyline	Sertraline	Statistics	
Characteristic	(N = 25)	(N = 42)	Test Result	p	(N = 38)	(N = 32)	Test Result	p
Marital status, N (%)								
Married	20 (80)	36 (86)	$\chi^2 = 1.33$	.25	29 (76)	19 (59)	$\chi^2 = 2.39$	.4
Not married	5 (20)	6 (14)			9 (24)	13 (41)		
Parity, N (%)[b]								
First child	10 (40)	21 (51)	$\chi^2 = 0.79$	.5	18 (47)	12 (39)	$\chi^2 = 1.33$	.3
Not first child	15 (60)	20 (49)			20 (53)	19 (61)		
Race , N (%)								
White	20 (80)	33 (79)	FE = 1.74	.5	33 (87)	21 (66)	FE = 6.3	.03
Black	5 (20)	6 (14)			3 (8)	10 (31)		
Other	0 (0)	3 (7)			2 (5)	1 (3)		
Education status, N (%)								
No college degree	16 (67)	27 (64)	$\chi^2 = 0.82$	.5	23 (61)	22 (71)	$\chi^2 = 0.82$	.4
College degree	8 (33)	15 (36)			15 (39)	9 (29)		
Breastfeeding status, N (%)[c]								
Breastfeeding at last week in study	9 (60)	15 (54)	$\chi^2 = 0.16$	.8	9 (47)	15 (62)	$\chi^2 = 1.0$	.4
Not breastfeeding	6 (40)	13 (46)			10 (53)	9 (38)		
Maternal age, mean (SD), y	29.0 (6.5)	29.2 (5.7)	t = 0.15[d]	.9	29.7 (5.9)	28.4 (6.2)	t = –0.93[e]	.4
Infant age, mean (SD), wk	6.0 (3.7)	5.9 (3.7)	t = 0.35[f]	.9	5.9 (3.7)	5.9 (3.7)	t = 0.08[g]	.9
HAM-D score, mean (SD)	26.8 (5.1)	24.4 (5.1)	t = 1.93[d]	.06	24.7 (7.2)	25.8 (5.9)	t = –0.86[d]	.4
ASEX score, mean (SD)	21.1 (6.3)	20.5 (6.4)	t = 0.35[f]	.7	22.5 (6.2)	22.1 (6.3)	t = –0.22[e]	.8

[a]Remission status analyses are based on 67 observations.
[b]Parity data were missing for 1 subject.
[c]Data available for 43 subjects.
[d]df = 65.
[e]df = 67.
[f]df = 61.
[g]df = 63.
Abbreviations: ASEX = Arizona Sexual Experience Scale, FE = Fisher exact statistic, HAM-D = Hamilton Rating Scale for Depression, MDD = major depressive disorder.

doses that were associated with remission were as follows: for sertraline-treated women, 75 to 200 mg/day; for nortriptyline-treated women, 75 to 150 mg/day.

Outcome Measures

The Arizona Sexual Experience Scale (ASEX)[30] was the measure of sexual function. It consists of 5 questions and a sixth open-ended question for information the subject wishes to provide. The response for each question is a value between 1 (most satisfied) and 6 (least satisfied). The HAM-D (discussed previously) was the outcome measure for depression and is a well-validated research instrument.[29] Both the ASEX and the HAM-D were administered weekly during the trial.

Statistical Methods

To describe the sample, comparisons of demographic and other characteristics of women (1) randomly assigned to nortriptyline versus sertraline and (2) remitted at 8 weeks versus not remitted at 8 weeks were completed with t tests for continuous measures and with χ^2 or Fisher exact statistics for categorical measures. To estimate the relationship between ASEX and HAM-D scores across the 8 weeks of treatment, mixed-effects regressions were used. Mixed-effects regression was also used to evaluate the significance of the main effects of time-dependent depression symptom scores, drug assignment, weeks treated with medication, and the interactions of depression symptom scores by time and drug assignment by time. The primary effect of interest was whether greater decreases in sexual concerns were observed in women whose depression symptom scores declined compared to women whose scores did not decline. In addition to the continuous ASEX scores, a dichotomized variable of concerns in 3 or more ASEX items was constructed. Responses on the 5 ASEX items were dichotomized at 1–3 (no difficulty) versus 4–6 (some difficulty). This dichotomized measure was used in logistic mixed-effects models with the ASEX dichotomy as the dependent measure.

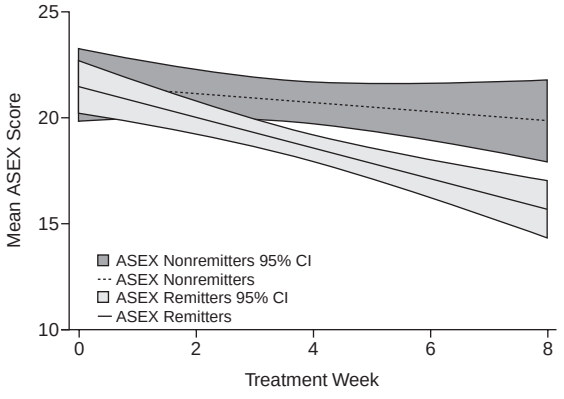
Models were developed with both the continuous HAM-D measure at each week and remission status at 8 weeks as predictor variables. These multivariable models were used to evaluate whether decreasing ASEX scores were related to decreasing depression symptoms. The multivariable models were also used to evaluate whether differences in sexual concerns for women in the two medication groups were present. Specific items on the ASEX were compared across time, remission status, and drug assignment with mixed-effects logistic regressions. Stata software, version 8 (Stata Corp, College Station, Tex.) was used for all analyses.

Table 2. Univariable and Multivariable Models of Continuous and Dichotomized ASEX Scores

	Continuous ASEX		Dichotomized Number of Areas With Sexual Concerns[a]	
Model	β-Coefficient	95% CI	Odds Ratio	95% CI
HAM-D scores, treatment week, and remission status				
HAM-D only[b]	0.25***	0.20 to 0.29	1.15***	1.10 to 1.20
Treatment week[c]	–0.63***	–0.77 to –0.50	0.69***	0.61 to 0.78
Remitter at 8 weeks[d]	–1.68	–4.26 to 0.90	0.32	0.09 to 1.09
HAM-D scores, treatment week, remission status by week in study interaction, medication assignment				
HAM-D	0.16***	0.10 to 0.23	1.08**	1.02 to 1.15
Treatment week	–0.12	–0.36 to 0.12	1.01	0.82 to 1.24
Remitter at week 8[d]	0.43	–2.23 to 3.09	1.83	0.34 to 9.83
Remitter by week	–0.29*	–0.57 to 0.01	0.70**	0.54 to 0.91
Medication assignment	–0.10	–2.51 to 2.32	2.35	0.60 to 9.26

[a]Dichotomized variable that indicates 0 = < 3 problem areas on ASEX reported; 1 = ≥ 3 problem areas on ASEX reported.
[b]Coefficient and odds ratio based on changes with 1 point change in the HAM-D scale.
[c]Week in study is used as a continuous linear variable. There was no evidence of a nonlinear component to this relationship (data not shown).
[d]Based on 67 women with follow-up data past week 3.
*p < .05.
**p < .01.
***p < .001.
Abbreviations: ASEX = Arizona Sexual Experience Scale, HAM-D = Hamilton Rating Scale for Depression.

Figure 1. Mean ASEX Total Scores by Remission Status[a]



[a]Remission status is based on remission (HAM-D score < 7) at 8 weeks of treatment.
Abbreviation: ASEX = Arizona Sexual Experience Scale.

RESULTS

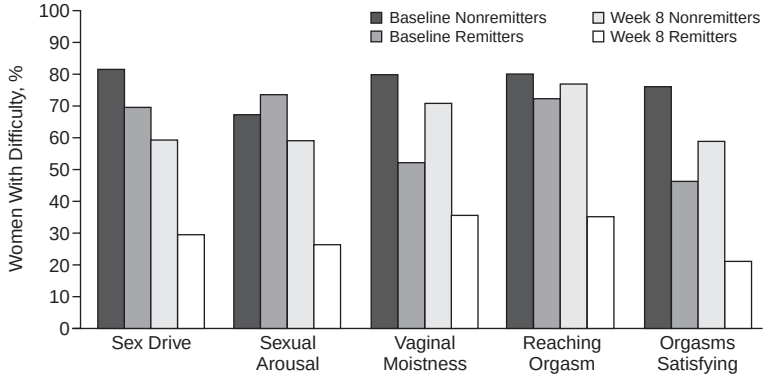
A total of 70 subjects aged 19–42 years (sertraline, N = 32; nortriptyline, N = 38) were available for analyses. As shown in Table 1, there were no significant differences at baseline in women's ages, educational status, marital status, parity, infant age at enrollment, or breastfeeding status for women who did or did not remit or between women assigned to sertraline or nortriptyline. There were more African American women randomly assigned to sertraline (p = .04). This difference in racial composition was discussed in the primary publication[28] and in a letter to the editor in response to that publication.[31] At baseline, the ASEX and HAM-D scores did not differ significantly between women who did or did not remit or with respect to assignment to nortriptyline versus sertraline (Table 1). At baseline, breastfeeding status was not significantly related to ASEX scores.

Table 2 presents summaries of the regression analyses. There were significant decreases in ASEX scores across the treatment trial; however, the ASEX score decreases were greater in the women who achieved remission from depression. In the multivariable models, the HAM-D score and the interaction of remission status by week were significant.

Figure 1 graphically displays the interaction of time by remission status for the continuous ASEX scores. Including the depressive symptom levels in the models decreased the importance of week in study to a nonsignificant level, which confirms the importance of reduction in depressive symptoms to improvement in ASEX scores. The main effect for drug assignment and interactions between remission status by drug assignment and time by drug assignment were not significant, which demonstrates that nortriptyline versus sertraline assignment had no impact on the trajectory of ASEX score improvement.

At entry into the randomized trial, 73% (N = 51) of the women reported problems in 3 or more areas of sexual concern compared to 37% (N = 26) at week 8. In our exploratory analyses of individual items from the ASEX, concerns about sex drive, vaginal moistness, and orgasms satisfying decreased over weeks of treatment independent of remission status (p < .007). For the item concern about sex drive, a larger decrease for the remitters was observed (p < .02). Remitters had fewer concerns about sexual

Figure 2. Percentages of Women With Some to Significant Difficulty on Items From the Arizona Sexual Experience Scale[a,b]



[a]Baseline values reflect the percentages of women who reported difficulty in specific areas at baseline grouped by remission status at week 8. Eight-week values reflect the percentage of the women who reported difficulty at 8 weeks grouped by remission status at 8 weeks.
[b]Graph labels were derived from specific questions on the Arizona Sexual Experience Scale:
Sex Drive: How strong is your sex drive?
Sexual Arousal: How easily are you sexually turned on?
Vaginal Moistness: How easily does your vagina become moist during sex?
Reaching Orgasm: How easily can you reach orgasm?
Orgasm Satisfying: Are your orgasms satisfying?

arousal or reaching orgasms ($p = .002$ for both; Figure 2). Treatment drug and the interaction drug by week in study were not significantly related to changes in any item ($p > .23$ for all).

DISCUSSION

We found that (1) women with higher pretreatment depression scores reported higher levels of sexual concerns and lower levels of sexual function, (2) the amount of improvement in depression symptom levels was positively associated with decreased sexual concerns and improved sexual functioning, and (3) sexual concerns significantly decreased across the 8 weeks of treatment similarly in both drug treatment groups. In our evaluation of individual items on the ASEX, women whose MDD remitted had fewer concerns about sex drive, and fewer concerns about sexual arousal and reaching orgasm.

To our knowledge, this is the first study to evaluate sexual function in postpartum women meeting full DSM-IV criteria for depression and its relationship to treatment response to 2 different classes of antidepressant medication. Not surprisingly, higher levels of sexual concerns were reported by women with higher depression symptom scores. This finding is consistent with results of previous studies documenting the association between sexual dysfunction and major depression at other times during the life span.[12,32–35]

Decreases in sexual concerns were observed across the 8-week study (total score and individual items on the ASEX) independent of assignment to nortriptyline, a tricyclic antidepressant, or to sertraline, a serotonergic agent. The decreasing trajectory was related specifically to decrease in depression scores rather than to the passage of time. This finding supports our hypothesis that the decline of reported sexual concerns is associated with the concurrent improvement in depressive symptoms. This observation is in line with previous data documenting that women show a direct relationship between antidepressant response and reduced sexual concerns, irrespective of antidepressant selected.[23] On the specific items on the ASEX, women whose MDD remitted showed improvement in each of the 3 phases of sexual physical response (sex drive, arousal, orgasm).

The strengths of our study include the randomized design that allowed us to directly compare the depression and sexual outcomes between the treatment groups in the same cohort. We used a validated instrument to assess sexual function[30] that includes some advantages over others, such as brevity and simplicity. We directly assessed sexual function using the instrument as a self-report measure rather than relying on spontaneous report. The use of a questionnaire that solicits specific information related to sexual function is widely considered to be a valid approach to the assessment of sexual dysfunction. By inquiring routinely about sexual concerns, clinicians can provide education about postpartum health in its entirety and, simultaneously, help the woman to find an effective strategy for addressing the problem. Moreover, we compared two classes of antidepressants, one of which (sertraline, a selective serotonin reuptake inhibitor) is commonly associated with sexual dysfunction.

Some limitations must be considered in interpreting the results. First, the sample size was relatively small and may not represent postpartum depressed women who do not participate in randomized clinical trials. Second, a placebo group would have strengthened the design; however, as has been discussed elsewhere,[28] the use of placebo for women with postpartum MDD represents an ethical dilemma because women and infants would be subjected to untreated depression. Moreover, because our aim was to evaluate the impact of 2 antidepressants on sexual function, we conducted a comparative study. Third, the findings are specific to postpartum women and may not be generalizable to antidepressant-treated women in general. In new mothers with depression, sexual dysfunction results from the combined effects of mood disorder and perineal recovery. Psychosocial variables such as changes in body image, marital satisfaction,

and the demands of motherhood would provide a more integrated picture of resuming sexual relations after giving birth. For example, De Judicibus and McCabe[8] reported that relationship satisfaction and quality strongly predicted the new mother's sexual desire. Conversely, a high-risk sample such as ours may be viewed as a particularly useful one in which to explore the relationships between sexuality, depression, and antidepressant treatment. Fourth, we were able to evaluate only the physical component of sexual function with the ASEX. Sexuality is a complex behavior, a human act within the complex dynamism of biologic, interpersonal, and cultural components.[36] To our knowledge, these factors have been the subjects of little empirical research.

In summary, our results confirm a direct relationship between antidepressant response and improved sexual function in postpartum women, irrespective of the antidepressant class and the passage of time.

Drug names: nortriptyline (Pamelor and others), sertraline (Zoloft and others).

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