A Double-Blind Study of Citalopram Versus Placebo in the Treatment of Compulsive Sexual Behaviors in Gay and Bisexual Men

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Objective: Compulsive sexual behavior (CSB) is a condition characterized by loss of control over sexual behavior and repeated negative consequences, including unsafe sex. Selective serotonin reuptake inhibitors have been found to reduce CSB symptomatology in open-label trials. The objective of this study was to conduct a preliminary double-blind, placebo-controlled evaluation of the efficacy, acceptability, and tolerability of citalopram in the treatment of CSB.

Method: Twenty-eight men who have sex with men who met the threshold for CSB on the basis of existing validated measures participated in a 12-week, double-blind trial of citalopram 20 to 60 mg/day to evaluate its effects on CSB symptoms. The primary efficacy measure was the Yale-Brown Obsessive Compulsive Scale-Compulsive Sexual Behavior. The study was conducted from June 2002 to April 2004.

Results: Significant treatment effects were obtained for sexual desire/drive (p < .05) and frequency of masturbation (p < .01) and pornography use (p < .05). Both groups reduced sexual risk, but did not differ significantly.

Conclusions: This study provides partial support for the effectiveness of citalopram for reducing symptoms of CSB in this population. Larger-scale trials are recommended to determine the public health benefits of this treatment.

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ompulsive sexual behavior (CSB) is characterized by sexual behaviors and fantasies that increase in frequency and intensity so as to interfere with personal, interpersonal, and/or vocational pursuits.¹ Nonparaphilic CSB² refers to "recurrent, intense sexually arousing fantasies, urges, and behaviors that are socially sanctioned (e.g., protracted promiscuity, compulsive masturbation, and substance use to enhance sexual pleasure), but lead to a loss of control over behavior and repeated negative consequences, for greater than 6 months' duration, so as to preclude or significantly interfere with the capacity for reciprocal affectionate activity."^{2(p351)} In turn, the disorder can be classified as paraphilic when the behaviors or fantasies are socially deviant (i.e., nonhuman objects, the suffering or humiliation of oneself or one's sexual partner, or children or other nonconsenting persons).^{1,3}

The prevalence of CSB has been estimated to be 3% to 6% in the general population and is considered to be more common in men and possibly in gay men.⁴ The association of CSB and sexual risk behavior merits public health attention. Having unprotected sex with multiple partners—particularly among populations with elevated human immunodeficiency virus (HIV) prevalence—

ners and more unsafe sex than those without CSB.⁶ There is no established treatment for CSB. Current clinical approaches include psychotherapy, self-help groups, and medications such as selective serotonin reuptake inhibitors (SSRIs). There have been no controlled clinical trials to test the efficacy of any form of treatment, though open trials of SSRIs have demonstrated some efficacy in reducing CSB symptomatology.^{1,2,7,8} Mechanisms for such effects might include reduced anxiety, reduced depression, or reduced sexual desire and performance, a well-documented side effect of these agents.^{7–9}

We conducted a randomized, parallel-group, placebocontrolled study to assess the efficacy and tolerability of citalopram during a 12-week course of treatment in 28 outpatient MSM presenting with nonparaphilic CSB.

METHOD

Participants were recruited from an assessment study of MSM reporting CSB (N = 183). Only those eligible on the basis of a comprehensive assessment using several CSB measures (see "Measures"), the Composite International Diagnostic Interview-Short-Form,¹⁰ and the Structured Clinical Interview for DSM-IV (SCID-IV)¹¹ were referred to this medication trial. Eligible participants were 18 years or older, reported sex with at least 2 male partners in the past 90 days, and scored at least moderately ill (definite, but generally manageable interference with psychological/social/occupational performance) on the Clinical Global Impressions scale (CGI),12 which was modified specifically for CSB (CGI-CSB). Participants could not have a psychiatric disorder severe enough to interfere with participation, suicidality, major depressive disorder, bipolar disorder, severe alcohol or drug dependence, significant abnormal physical or laboratory results, current treatment with an SSRI, or recent (past 90 days) HIV seroconversion. Study eligibility was ascertained a second time at the baseline clinical interview of this medication trial conducted by the participants' research psychiatrist. Fourteen of 42 persons screened were excluded; 28 were randomly assigned to treatment.

Procedure

Participants were randomly assigned to receive either a flexible-dose citalopram trial (20–60 mg/day; 1-3 capsules/day; N = 13) or placebo (1–3 capsules/day; N = 15) in a double-blind fashion. The trial consisted of an initial psychiatric assessment, a 12-week treatment period, and a 2-week treatment taper. A URN randomization procedure¹³ was designed to balance HIV status, CSB score, depression, and substance use. Participants met every 2 weeks with their study psychiatrist and monthly with a research assistant. Of 28 men randomized, 26 completed the study, and 2 dropped out at week 4 (both in the citalopram group). Neither of the participants who dropped out reported sexual side effects (SSE). All 28 participants were included in the analyses.

The initial and minimum dose was 20 mg (1 capsule) daily for the first 2 weeks. A flexible titration schedule was employed for both groups with increments of 20 mg every 14 days based on therapeutic response and tolerance up to a maximum of 60 mg per day. Study medication was provided in prepackaged coded plastic bottles containing a 2-week supply of identical 20-mg citalopram or placebo capsules. Adherence to medication was assessed throughout the study through pill counts, participant assessment, and citalopram blood level drawn at weeks 4 and 12 of the treatment period. If a participant developed sexual dysfunction (e.g., delayed ejaculation), the dose was decreased (N = 5) and/or he was given cyproheptadine 4 mg (N = 4).¹⁴

The study protocol was approved by the Mount Sinai School of Medicine and the Centers for Disease Control and Prevention Institutional Review Boards. All participants signed approved informed consent forms after the study procedures had been fully explained. The study was conducted from June 2002 to April 2004.

Measures

Yale-Brown Obsessive Compulsive Scale-The Compulsive Sexual Behavior (YBOCS-CSB; J.M., F.M., T.W.I., et al., unpublished manuscript), the primary efficacy measure, was used as a global summed index of compulsive sexual thoughts and behaviors across behavioral subtypes (pornography, anonymous partner cruising, Internet, masturbation). The YBOCS-CSB measures thoughts and behaviors separately in 5 domains including time spent, distress, interference, loss of control, and ability to resist. Originally created to assess symptoms of obsessive-compulsive disorder (OCD),¹⁵ it has been successfully adapted to assess thoughts and behaviors related to pathological gambling,16 body dysmorphic disorder,¹⁷ and substance use disorders.¹⁸ The 10-item scale ranges from 0 to 40. In the current sample, internal consistency coefficients over the course of the trial ranged from a low of .81 (baseline) to a high of .91 (week 10), indicating good reliability.

The Compulsive Sexual Behavior Inventory (CSBI)¹⁹ sexual control subscale ($\alpha = .96$) was included as a measure of concurrent validity with the YBOCS-CSB. Lower scores on the CSBI are indicative of greater CSB. The CGI-CSB was used to assess global improvement over the course of the trial as compared to baseline functioning

on a scale from 1 (very much improved) to 7 (very much worse). Ratings from the YBOCS-CSB and CGI-CSB were subject to review by a team of 3 study psychiatrists who blindly scored each participant after the treating study psychiatrist presented the case to the team. Although we do not have reliability data on this method, interrater consistency was very high. When disagreement occurred, the rating obtained by the majority was used.

The Timeline Follow-Back²⁰ was used to obtain a daily history of sexual behavior including frequency, partner HIV status (positive, negative, or unknown), partner type (main, anonymous, or known), sex type (oral or anal; insertive or receptive), and risk level (protected vs. unprotected). In the current study, outcome variables obtained via the Timeline Follow-Back included number of sexual partners, oral and anal sex acts, risky anal sex acts, risky oral sex acts, and several combinations of these variables. Risky anal sex included all anal sex acts without the use of a condom regardless of HIV serostatus. Risky oral acts included oral receptive without a condom for HIV-seropositive participants.

Although participants with a current diagnosis of major depressive disorder were ineligible for the study, the Hamilton Rating Scale for Depression (HAM-D)²¹ was used to examine the effects of citalopram on the continuum of depressive symptomatology.

We included several questions assessing sexual desire, behavior, and satisfaction. Strength of sexual desire/drive was adapted from the Arizona Sexual Experience Scale²² and was measured using a scale ranging from 1 (extremely weak) to 6 (extremely strong). Frequency of masturbation was measured using a scale ranging from 0 (less than once per month) to 7 (4-6 times per day). Participants were asked to estimate the number of hours per week spent viewing pornography and using the Internet for sexual purposes (i.e., cruising for sex) and fantasizing about sex (all thoughts and urges when not engaging in sexual activities). Participants who did not engage in the sexual behavior were coded as spending zero hours per week. We also measured sexual satisfaction for specific sexual behaviors using a scale ranging from 0 (extremely satisfied) to 6 (extremely dissatisfied). Only participants who reported engaging in the specific behavior were assessed for sexual satisfaction in that domain. Sexual side effects were assessed every 2 weeks by study psychiatrists based on participants' self-report using a 5-point scale ranging from 0 (low) to 4 (high).

Data Analysis

Main effects for CSB, SSE, and sexual satisfaction were analyzed via repeated-measures analysis of variance, which assessed condition differences over time for indices of CSB, SSE, and sexual satisfaction. Square root transformations were used for the positively skewed vari-

ables. The measure of effect was treatment-by-time interaction. Baseline scores and scores over the final 4 weeks of treatment were included in analyses; since CSB tends to be variable, we averaged the last 4 weeks of treatment to obtain a more stable measure of CSB, as in previous studies.²³ Of the 4 variables that were measured every 2 weeks (YBOCS-CSB, CGI-CSB, HAM-D, and SSE), we averaged the week 10 and week 12 scores to provide the average for the final month of treatment. Week 4 scores were used for both study dropouts. For conditionby-SSE analyses, the numbers of SSE per week were summed and then recoded into dichotomized variables as ever/never present during the trial. Because the purpose of the trial was to reduce libido and sexual arousal, these 2 SSE variables were not included in the summed end-oftreatment SSE variable. Group differences between individual SSE were measured via χ^2 or Fisher exact test (2sided). After main effects were assessed, 2 analyses of covariance were performed to assess the influence of the severity of the SSE indicated over the last 28 days of treatment. This was achieved by including the severity of the summed SSE over the final 28 days as a covariate in each significant main effect equation. This procedure was used to test for the mediating effects of SSE.²⁴

RESULTS

Participants

The mean age of the study sample was 36.8 years (SD = 8.2). Twenty-four identified as gay, and 4 identified as bisexual. The majority of participants had at least some college education (N = 25); 18 were employed full- or part-time. The average income was \$30,000 to \$39,000. Three participants (10.7%) were HIV-seropositive, and 22 (78.6%) had a sexually transmitted infection other than HIV in their lifetime, with 13 (46.4%) having more than 1. Six men (23.1%) were diagnosed with herpes. With regard to past treatment for CSB, 6 men (23.1%) in the sample had received outpatient psychotherapy, 1 (3.8%) had taken a medication, and 5 (19.2%) had attended self-help groups for CSB (percentages are based on the numbers of subjects who answered the questions).

Adherence

Of the 26 study completers, 98% of appointments were kept. The average time between twice-monthly appointments was 15.27 days (SD = 1.43; range, 8–27 days). Blood citalopram levels were collected at week 4 and at the end of treatment to determine adherence to the study protocol. Results indicate that all participants in the placebo condition had nondetectable levels, while all participants in the citalopram condition had detectable levels; week 4 mean = 66.6 ng/mL (SD = 46.65), week 12 mean = 72.64 ng/mL (SD = 60.59). The mean daily dos-

Variable	Citalopram (N = 13), ^b Mean (SD)		Placebo (N = 15), Mean (SD)		Between-Group Differences		Combined Group
	Baseline	Week 12	Baseline	Week 12	F ^c	р	Change, p
YBOCS-CSB	27.30 (4.81)	16.92 (6.71)	25.60 (5.59)	17.40 (6.48)	0.85	.362	.000
CSBI ^d	26.84 (5.55)	34.69 (6.16)	30.60 (7.39)	39.00 (6.87)	0.06	.809	.000
CGI-CSB	5.33 (0.88)	2.42 (0.90)	5.27 (1.16)	2.20 (0.78)	0.10	.756	
Desire/drive to have sex ^e	5.58 (0.67)	4.33 (0.88)	5.27 (0.70)	4.87 (0.74)	7.80	.011	.000
Frequency variables							
Masturbation per week ^f	4.69 (1.50)	2.69 (1.03)	4.47 (1.73)	3.73 (1.71)	7.87	.009	.000
Hours of Internet use per week ^g	8.69 (10.50)	6.15 (10.54)	5.73 (6.29)	7.20 (10.17)	3.00	.092	.331
Hours of pornography use per week ^g	7.08 (8.86)	2.31 (1.90)	6.40 (7.42)	5.93 (4.62)	4.30	.048	.223
No. of partners per month ^g	14.4 (10.61)	9.84 (9.94)	9.93 (10.77)	6.07 (7.52)	0.19	.668	.003
No. of oral and anal sex acts per month ^g	24.07 (20.16)	12.84 (17.18)	15.67 (13.98)	9.73 (12.01)	1.16	.291	.000
No. of risky oral and anal sex acts per month ^g	4.69 (8.21)	3.08 (6.97)	2.87 (4.29)	1.47 (3.22)	0.28	.604	.048
Distress measure							
HAM-D score	2.69 (2.62)	1.50 (1.39)	2.33 (3.67)	0.67 (1.23)	0.22	.643	.009
Satisfaction variablesh							
No. of sex partners	3.08 (1.66)	3.23 (1.42)	3.27 (1.70)	3.47 (1.36)	0.02	.882	.581
Frequency of masturbation	2.42 (1.56)	2.83 (1.57)	2.27 (1.83)	2.47 (1.73)	0.06	.805	.484
Frequency of pornography use ⁱ	2.84 (1.44)	2.18 (0.87)	2.93 (1.73)	2.79 (1.85)	1.01	.326	.127

Table 1. Main Outcome Effects: Baseline and Week 12 Raw Scores, Treatment Group Differences, and Combined Sample Change From Baseline to Week 12^a

^aAll data presented as raw scores.

^bIncludes week 4 scores of 2 study dropouts.

 c df = 22 for satisfaction with pornography; df = 26 for all other variables.

^dLower scores on the CSBI are indicative of greater compulsive sexual behavior.

^eMeasured on a scale from 1 (extremely weak) to 6 (extremely strong).

^fMeasured on a scale from 0 (less than once per month) to 7 (4–6 times per day). Baseline scores indicate about 1 time per day, g Square root transformations.

^hSatisfaction variables were measured on a scale from 0 (extremely satisfied) to 6 (extremely dissatisfied). Scores reflect the subjects' satisfaction with these variables.

ⁱN = 24 (10 citalopram, 14 placebo).

Abbreviations: CGI-CSB = Clinical Global Impressions scale-Compulsive Sexual Behavior, CSBI = Compulsive Sexual Behavior Inventory, HAM-D = Hamilton Rating Scale for Depression, YBOCS-CSB = Yale-Brown Obsessive Compulsive Scale-Compulsive Sexual Behavior.

ages of citalopram were 25.5 mg at week 4 and 43.36 mg at week 12.

Treatment Effects

Participants in both conditions significantly reduced the majority of their CSB symptoms over the course of the trial (Table 1). Significant treatment effects favoring the citalopram group included a significant decrease in desire/drive for sex, F = 7.80, df = 2,26; p < .05; frequency of masturbation, F = 7.87, df = 2,26; p < .01; and hours of pornography use per week, F = 4.30, df = 2,26; p < .05. Although the medication group generally had greater CSB problem severity, no significant differences were observed at baseline between groups (p values > .10).

Sexual Side Effects

Men in the citalopram group reported delayed ejaculation significantly more often than placebo recipients ($\chi^2 = 5.11$, p < .05). Secondary analysis revealed that SSE mediated treatment effects on masturbation and pornography use, as the main effect between condition differences for these parameters became nonsignificant when SSE severity was included as a covariate, F = 2.43,

df = 3,25; p > .10 and F = 1.55, df = 3,25; p > .10, respectively. In contrast, treatment and placebo condition differences remained with regard to sexual desire/drive, F = 8.03, df = 3,25; p < .01, when SSE were entered into the equation.

Sexual Satisfaction

Overall, level of sexual satisfaction remained fairly stable over the course of the trial across conditions (see Table 1). We also assessed the relationship between the severity of SSE and all satisfaction variables by regressing baseline satisfaction and SSE at end of treatment onto end of treatment satisfaction variables. The severity of SSE was not indicative of lower sexual satisfaction in any domain assessed (all p values > .10).

DISCUSSION

Results offer tentative support for the effectiveness of citalopram in reducing aspects of CSB, namely the drive/ desire for sex and frequency of masturbation and for the compulsive use of pornography. Reductions in desire and time-consuming masturbation may result in fewer negative consequences. While the effect on masturbation and pornography use frequency was mediated by SSE, no reduction in overall sexual satisfaction was observed, and 85% of citalopram recipients completed the study, suggesting that SSE were sufficiently modest so as not to be associated with discontinuation of active medication, sexual performance dissatisfaction, or dropping out of the study. Although masturbation and the compulsive use of pornography were not the primary target behaviors for this study, this is a noteworthy clinical effect, as timeconsuming pornography dependence is a distinct CSB phenomenon, and a positive treatment effect on this condition is of clear value. This is particularly salient as the reported downloading of and dependence on pornography, including child pornography, in the general population (i.e., not particular to the gay and bisexual male population of our study) have become a serious clinical and societal problem since the advent of the Internet.²⁵

No significant effects on partnered sexual behaviors were observed, suggesting that the potential public health impact of pharmacotherapy of this disorder may be limited. However, our sample size for this preliminary study was small; an effect might emerge with more statistical power. Overall, participants in both treatment arms reduced their sexual risk, suggesting the "readiness" of participants to change their behavior. Our findings suggest that different processes may mediate reductions in sex drive/desire versus partnered sex. The purposes served by the latter are numerous and may include social and selfesteem needs beyond mere sexual release.

Low baseline scores on the HAM-D were most likely a function of our exclusion of depressed patients from this trial to control for changes in CSB as a consequence of improvement in depressive symptoms. We did not assess current attention deficit disorder, a condition often comorbid with CSB,²⁶ which may have affected results as citalopram would not have treated this disorder.

If CSB is a variant of OCD, it may be that longer trials using higher doses would be necessary to reveal an effect. In OCD treatment, 40% to 60% of patients do not respond to adequate treatment trials with SRIs.^{27,28} In our study, all subjects, regardless if in the treatment or placebo arm, decreased their CSB early in the trial. With the hypothesis that CSB may be an OCD-related disorder, a longer trial may have given the opportunity for treatment arm subjects to benefit from a longer and higher-dose exposure to citalopram, and for placebo subjects to return closer to baseline after the initial reduction in CSB.

For this preliminary study, our sample size was small, and a pharmacologic treatment effect may have been masked by this factor as well as a high placebo response rate, short duration of active treatment, and low base rate of specific sexual behaviors. An additional limitation of this study was the study participants' obvious bias toward wanting to reduce problematic sexual behaviors, and anticipating doing so could have influenced both treatment groups. Moreover, the detailed evaluation and frequent reporting of target sexual behaviors throughout the study's duration may have provided an active placebo effect sufficient to make it difficult to distinguish the citalopram group from the placebo group. Shame associated with disclosing CSB to a provider could have interfered with the ability of the psychiatrist to properly prescribe citalopram. These same factors have contributed to the controversy as to the efficacy of antidepressant pharmacotherapy for the treatment of major depression.²⁹

The present study was the first to test an SSRI agent as a treatment for nonparaphilic CSB. It builds on uncontrolled studies, as well as clinical observation. This preliminary effort should not be taken as definitive. Alternatively, our study suggests the need of combining pharmacotherapy with other interventions (pharmacologic, nonpharmacologic) to counteract the lack of effect on partnered sex, especially if unsafe sexual activity is present. Further research to rigorously test pharmacologic and behavioral interventions to reduce CSB and sexual risk taking is needed. Gay and bisexual men with CSB, in these days of the HIV/AIDS pandemic, seek help in substantial numbers, and it is in the best interests of society as well as the individual men that they receive effective therapy. It is in the best interests of all males afflicted with CSB to receive treatments that have been empirically validated, including treatment combinations.

Drug name: citalopram (Celexa and others).

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