Escitalopram in the Treatment of Impulsive-Compulsive Internet Usage Disorder: An Open-Label Trial Followed by a Double-Blind Discontinuation Phase

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Background: Isolated reports suggest that escitalopram may be effective for impulsive-compulsive Internet usage disorder (IC-IUD), an impulse-control disorder characterized by excessive time spent on the Internet at the expense of occupational, relationship, and social activities. To assess the safety and efficacy of escitalopram in IC-IUD, we conducted a 10-week, open-label trial followed by a 9-week, double-blind, placebo-controlled discontinuation phase.

Method: From December 2002 to October 2004, 19 adult subjects with IC-IUD (defined as time consuming, uncontrollable, distressing, and resulting in social, occupational, or financial difficulties) were enrolled. Escitalopram was started at 10 mg/day, then increased and maintained at 20 mg/day for 10 weeks at the end of which completers were randomly assigned to placebo or escitalopram for 9 additional weeks. Two key outcome measures were used: hours spent weekly in nonessential Internet use and overall clinical response (subjects rated "much improved" or "very much improved" on the Clinical Global Impressions-Improvement scale [CGI-I]).

Results: Fourteen subjects completed the entire study. At the end of the 10th week of open-label escitalopram, Internet usage decreased significantly from a mean of 36.8 hours/week at baseline to 16.5 hours/week (paired t test: $t = 3.58$; $p = .002$). In addition, 64.7% of the sample (N = 11) were considered CGI-I responders. At the end of the double-blind phase, there were no significant differences in outcome measures between patients taking placebo compared to escitalopram (analysis of variance with repeated measures, $p > .05$).

Conclusion: Patients showed a significant improvement of IC-IUD symptoms during the open-label escitalopram phase. There was no significant difference between the escitalopram and placebo groups at the end of the subsequent double-blind phase; both groups maintained the gains made in the initial open-label treatment. Larger controlled trials are needed to investigate the efficacy of this and other pharmacologic agents in the treatment of IC-IUD.

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Impulsive-compulsive Internet usage disorder (IC-IUD), also referred to as Internet addiction, has only recently appeared in psychiatric literature[1,2] as a diagnosis describing uncontrollable and damaging use of the Internet. Currently, patients with IC-IUD could receive the diagnosis of impulse-control disorder not otherwise specified (ICD-NOS),[3] a category including disorders such as impulsive-compulsive sexual behaviors, impulsive-compulsive skin picking, and impulsive-compulsive shopping.[4] They are called impulsive-compulsive disorders due to the impulsive features (arousal) that initiate the behavior and the compulsive drive that causes the behaviors to persist over time.

Some subjects with IC-IUD report increasing amounts of time spent Web surfing, gambling, shopping, or exploring pornographic sites. Others report spending time in chat rooms or corresponding by e-mail. Frequently, these subjects develop a preoccupation with the Internet, a need for escape to the Internet, and increasing irritability when trying to cut back on Internet use. Ultimately, their attempt to cut back is unsuccessful. Functional impairments as a result of problematic Internet use include marital or family strife, job loss or decreased job productivity, legal difficulties, or school failure.[5] IC-IUD has been reported in any age, social, educational, and economic range.[6] However, while previous studies tended to stereotype the classical Internet-addicted patient as a young introverted man,[7,8] recent investigation has shown increasing rates of this disorder among women,[6] as a result of the increased availability of the Internet. The prevalence of IC-IUD is not known, and most of the studies in the field have been

conducted with small samples. People enrolled, moreover, frequently had comorbid psychiatric diagnoses.[9] A recent American nationwide survey[10] reported a prevalence rate of 0.7% for problematic Internet use. In a previous study, Shapira and colleagues[2] found that all Internet addicted subjects also met the DSM-IV[3] definition for ICD-NOS. Moreover, studies assessing comorbidity rates between obsessive-compulsive disorder (OCD) and IC-IUD estimated that up to 15% of Internet addicted subjects met criteria for current OCD, and 10% to 20% met criteria for lifetime OCD.[2,9,11]

Most treatment strategies for IC-IUD involve behavioral therapy techniques, with the treatment goal of limiting the amount of time on the Internet rather than requiring abstinence, as is done with many other addictions such as substance abuse. Self-help groups (both on and offline) represent another treatment alternative. To date, no controlled pharmacologic studies in subjects with IC-IUD have been published. Previously, Sattar and Ramaswamy[12] reported the case of a 31-year-old man with severe Internet addiction successfully treated with escitalopram (10 mg/day). More recently, some studies assessed the efficacy and tolerability of escitalopram across different impulsive-compulsive disorders such as kleptomania,[13] trichotillomania,[14,15] pathological gambling with co-occurring anxiety,[16] and compulsive buying,[17] reporting mixed results. The goal of the present study was to examine the efficacy and tolerability of escitalopram in the treatment of IC-IUD.

METHOD

Advertisements and media coverage were utilized to recruit adults aged 18 years and older with IC-IUD defined as (1) uncontrollable, (2) distressing, (3) time consuming, and (4) resulting in social, occupational, and/or financial difficulties. These symptoms, moreover, did not solely occur during manic/hypomanic episodes. All subjects gave written informed consent to participate after receiving a full explanation of the study protocol, which had been approved by the Mount Sinai School of Medicine Institutional Review Board. Lifetime comorbid conditions were determined by the Structured Clinical Interview for DSM-IV Axis I.[18] Exclusion criteria included comorbid organic or psychotic mental disorders, mental retardation, substance abuse or dependence within the past 3 months, personality disorders severe enough to interfere with study participation, and risk of suicide. If a comorbid disorder was present, IC-IUD had to be the primary disorder, i.e., causing the most distress and dysfunction and providing the primary motivation to seek treatment. Subjects were enrolled in the study from December 2002 to October 2004.

The study was conceived as a 19-week prospective trial including 2 consecutive phases: (1) a 10-week, open-label phase to evaluate the efficacy and tolerability of escitalopram in subjects with IC-IUD and (2) a 9-week, double-blind, placebo-controlled discontinuation phase to assess eventual differences between escitalopram and placebo in terms of discontinuation effects as well as relapses.

Nineteen subjects (12 men and 7 women) meeting IC-IUD inclusion criteria were started on escitalopram at a dose of 10 mg/day and raised to 20 mg/day during the second week of treatment.

Primary outcome measures were time spent in nonessential Internet use (hours/week) and global improvement as measured by the Clinical Global Impressions-Improvement scale (CGI-I).[19] Responders were defined a priori as those subjects with CGI-I scores of 1 or 2 ("very much improved" or "much improved"). Secondary outcome measurements included the Barratt Impulsiveness Scale (BIS),[20] including the "motor," "cognitive," and "nonplanning" subscales, and the IC-IUD version of the Yale-Brown Obsessive Compulsive Scale (YBOCS),[21] including obsession and compulsion subscales. The IC-IUD-YBOCS is a clinician-administered scale with item ratings for obsessions and compulsions related to impulsive-compulsive Internet use (i.e., time spent, degree of interference, distress, resistance, and success in resisting). This scale was developed for this study based on the recently validated versions of the YBOCS for compulsive shopping[22] and pathological gambling.[23] Primary and secondary outcome measures were assessed at screening; at baseline; and at the end of weeks 2, 4, 6, 8, 10, 13, 16, and 19. Safety and tolerability were assessed at each visit after baseline using spontaneously reported events and rates of discontinuation for adverse events.

In the open-label phase, baseline to 10th week changes in outcome measures were analyzed for significance with paired t tests. In the double-blind phase, week 10 to endpoint changes in outcome measures between escitalopram and placebo were analyzed using analysis of variance (ANOVA) with repeated measures. In addition, the number of CGI-I responders (coding 1 or 2 as response) was computed at the end of both phases.

For all the statistical analyses, the α level of significance was set at .05 and was not adjusted for multiple comparisons. All the statistical analyses were performed using the SPSS for Windows software (version 14.0; SPSS, Inc., Chicago, Ill.).

RESULTS

10-Week Open-Label Phase

Nineteen subjects (12 men and 7 women) were enrolled. Demographic and baseline clinical characteristics of the sample are shown in Table 1. Most subjects (63%, N = 12) had engaged in impulsive-compulsive Internet use for at least 3 years; a majority of subjects (63%,

Table 1. Baseline Demographic and Clinical Characteristics of Study Subjects With Impulsive-Compulsive Internet Usage Disorder

Characteristics	Enrolled (N = 19)	Open-Phase Completers (N = 17)	Open- and Double-Blind Phase Completers (N = 14)
Age, mean ± SD, y	38.5 ± 12.0	37.5 ± 12.0	40.0 ± 11.5
Sex, N (%)			
Women	7 (37)	6 (35)	4 (29)
Men	12 (63)	11 (65)	10 (71)
Marital status, N (%)			
Single	13 (68)	12 (71)	10 (71)
Married	4 (21)	3 (18)	2 (14)
Divorced	2 (11)	2 (12)	2 (14)
Occupational status, N (%)			
Employed full-time	12 (63)	8 (47)	6 (43)
Employed part-time	5 (26)	5 (29)	5 (36)
Unemployed	2 (11)	4 (24)	3 (21)
Age at onset, mean ± SD, y	35.5 ± 12.0	34.5 ± 12.0	37.0 ± 11.5
Subjects with at least 1 comorbid psychiatric disorder (Axis I and/or II), N (%)	12 (63)	11 (65)	10 (71)
Internet use main subtype, N (%)			
E-mail	4 (21)	3 (18)	3 (21)
Pornography	4 (21)	4 (24)	3 (21)
Searching	3 (16)	4 (24)	4 (29)
Dating	3 (16)	3 (18)	2 (14)
Other (game, travel, blog, shopping)	5 (26)	3 (18)	2 (14)

N = 12) started this behavior after age 30. Most subjects (63%) were employed full-time. Patients were involved in different subtypes of Internet use such as e-mail, visiting pornographic- or gambling-related sites, searching or dating via the Internet, or several concomitant activities. In addition, 63% of the sample (N = 12) presented comorbid disorders, especially major depression and social anxiety disorder.

At baseline, patients showed a mean Internet use of 36.8 (SD ± 27.2) hours/week, a mean CGI-I total score of 3.83 (SD ± 1.04), a mean IC-IUD-YBOCS total score of 23 (SD ± 5), and a mean BIS total score of 42.0 (SD ± 19.7) (Table 2). Seventeen patients out of 19 (89.5%) completed the first 10 weeks of treatment. Neither dropout was due to side effects nor adverse events. At the end of the 10th week, primary outcome measures showed a statistically significant decrease, with a mean number of weekly hours spent on the Internet of 16.5 (SD ± 9.4) (paired t test: $t = 3.58$; $p = .002$) and a mean CGI-I total score of 1.8 (SD ± 1.0) (paired t test: $t = 5.18$; $p < .0001$) (Table 2). Eleven patients out of 17 (64.7%) were considered CGI-I responders ("very much improved" or "much improved"). In addition, the majority of secondary outcome measures indicated significant improvement as well, with total mean scores at the end of the 10th week for the IC-IUD-YBOCS of 10.5 (SD ± 4.4) (paired t test: $t = 8.21$; $p < .0001$) and for the BIS "nonplanning" subscale of 15.64 (SD ± 6.55) (paired t test: $t = 2.47$; $p = .025$) (Table 2). The most frequently reported side effects were drowsiness and nausea, which were modest and limited to the first 3 weeks of treatment.

9-Week, Double-Blind, Placebo-Controlled Phase

At the end of the 10th week, all patients who completed the first open phase of treatment (N = 17) were randomly assigned to receive escitalopram or placebo for 9 additional weeks in double-blind conditions. Fourteen patients completed the second phase of the study. The 3 dropouts, 2 in the escitalopram group and 1 in the placebo group, were not related to side effects or adverse events. The most frequently reported side effects in the escitalopram group included fatigue and sexual side effects, whereas patients taking placebo did not report any side effects. The ANOVA with repeated measures did not show any statistically significant difference in either primary or secondary outcome measures at the conclusion of the second phase of the study (*hours/week on the Internet:* time effect $F = 0.04$, $p > .9$; time × treatment effect $F = 0.35$, $p > .5$; treatment effect $F = 0.12$, $p > .7$; *CGI-I total score:* time effect $F = 0.514$, $p > .4$; time × treatment effect $F = 1.01$, $p > .3$; treatment effect $F = 0.521$, $p > .4$; *YBOCS total score:* time effect $F = 0.009$, $p > .9$; time × treatment effect $F = 0.03$, $p > .8$; treatment effect $F = 0.016$, $p > .9$).

DISCUSSION

To date, IC-IUD is not formally included in any of the major psychiatric diagnostic systems, although patients with IC-IUD can be diagnosed with ICD-NOS.[3] Nevertheless, several authors have pointed out that problematic Internet use has spread widely over recent years, as supported by growing interest and increasing investigation in this field. Researchers are focusing their efforts on identifying precise and reliable features of IC-IUD in terms of phenomenology,[9] epidemiology,[4,10] and, more recently, psychopharmacology.[12,24]

In the present study, people with IC-IUD were characterized by a more mature current age and age at onset than traditionally reported.[7,8] In addition, most subjects were single, were employed full-time, and presented with at least 1 comorbid psychiatric disorder. The presence of psychiatric comorbidity seems to be characteristic of IC-IUD, as reported in several studies[2,9,11,25]; however, whether Internet addiction represents a cause or consequence of these disorders remains to be elucidated. For some individuals, in fact, the excessive Internet use may be entirely accounted for by another Axis I disorder such as pathological gambling or impulsive-compulsive sexual behaviors; thus, Internet use is functioning simply as another outlet for that disorder rather than being an additional disorder.[4]

Table 2. Ratings of Impulsive-Compulsive Internet Usage Disorder (IC-IUD) at Baseline, at the End of the Open-Label Phase (10th week), and at Endpoint After the Double-Blind, Placebo-Controlled Phase (19th week)[a]

Measure	Baseline Score, Enrolled (N = 19)	End of Week 10 Score, Open-Phase Completers (N = 17)	End of Week 19 Score, Open- and Double-Blind Phase Completers (N = 14)	
			Escitalopram (N = 7)	Placebo (N = 7)
Hours/week on the Internet	36.8 ± 27.2	16.5 ± 9.4[b]	15.9 ± 8.8	16.12 ± 8.83
IC-IUD-YBOCS				
Total score	23.1 ± 5.0	10.47 ± 4.33[c]	10.7 ± 4.4	10.55 ± 4.38
Obsessions	9.33 ± 3.48	4.23 ± 2.30[d]	4.33 ± 2.35	4.3 ± 2.3
Compulsions	13.61 ± 2.85	6.23 ± 3.09[e]	6.5 ± 3.3	6.2 ± 3.2
CGI-I score	3.83 ± 1.04	1.76 ± 0.97[f]	1.65 ± 0.85	1.7 ± 0.9
BIS				
Total score	42.0 ± 19.7	39.88 + 18.94	40.1 ± 18.6	40.2 ± 19.2
Nonplanning	18.8 ± 7.6	15.64 ± 6.55[g]	16.1 ± 6.9	15.93 ± 6.40

[a]All values are shown as mean ± SD.
[b]Paired t test: t = 3.58; p = .002.
[c]Paired t test: t = 8.21; p < .0001.
[d]Paired t test: t = 6.26; p < .0001.
[e]Paired t test: t = 7.81; p < .0001.
[f]Paired t test: t = 5.18; p < .0001.
[g]Paired t test: t = 2.47; p = .025.
Abbreviations: BIS = Barratt Impulsiveness Scale, CGI-I = Clinical Global Impressions-Improvement scale, IC-IUD-YBOCS = IC-IUD Yale-Brown Obsessive Compulsive Scale.

The primary aim of the present study was to investigate the efficacy and safety of escitalopram, a selective serotonin reuptake inhibitor, in subjects suffering from IC-IUD. During the first open-label treatment phase, escitalopram showed a consistent reduction of all primary (weekly hours spent on the Internet and CGI-I scale) and secondary (BIS and IC-IUD-YBOCS) outcome measures. These results may be interpreted as supporting the inclusion of IC-IUD in the obsessive-compulsive spectrum disorders.[26] In this group of disorders, in fact, serotonin reuptake inhibitors (SRIs) are often one of the most effective treatments,[4,26,27] and escitalopram might have specifically improved the obsessive, compulsive, and impulsive features of IC-IUD. During the second double-blind controlled phase, however, the 2 groups of patients did not show any significant difference. Notably, the scores on the primary and secondary outcome measures were unchanged from the end of the open-label treatment; both groups maintained their gains. It may be speculated that 9 additional weeks were not enough for the effect to be lost in the placebo group or for additional gains to be made in the escitalopram group. Nevertheless, the possibility of a placebo response during the first open phase that was maintained during the subsequent double-blind phase in both groups, although less likely, cannot be ruled out.

Recent studies by Koran and colleagues used a similar design as the present trial to assess the efficacy of escitalopram in patients suffering from kleptomania[13] or impulsive-compulsive buying disorder,[17] conditions also on the compulsive-impulsive spectrum.[28] Both studies had a robust rate of response during the first open phase, similar to the present study; however, different results for the subsequent double-blind phase were found (i.e., subjects taking escitalopram had a similar rate of relapse as those taking placebo). Nevertheless, the studies by Koran's group differed from the present trial, having a shorter open treatment phase (7 weeks vs. 10 weeks) and in the study performed in patients with kleptomania, a longer double-blind phase as well (17 weeks vs. 9 weeks). It is possible that the shorter duration of active treatment in both of Koran's studies resulted in more relapses in both placebo and escitalopram groups during the subsequent double-blind phase compared to the present trial. On the other hand, it might be speculated that in the present study, longer active treatment in the open phase produced a sustained response during a shorter double-blind phase compared to Koran's studies. Ultimately, it is possible that a modification in the duration of active treatment may result in a different outcome and that longer periods of active treatment and follow-up are needed to explain different trends of response and relapse in patients with impulsive-compulsive disorders. In addition, the possibility to combine clinical trials with imaging studies of the patients' brains would allow researchers to directly visualize brain activity related to compulsive behaviors as well as to detect eventual differences in the brain activation patterns of subjects who respond to the drug compared to those who do not.

The literature on SRI treatment of IC-IUD does not yet provide a clear guide for clinicians. Although IC-IUD and OCD show many similarities, such as repetitive behaviors and intrusive thoughts, there are also differences between them. The impulse-control disorders, in fact, seem to have a slightly different pharmacologic response than the compulsive disorders[4,29] and show less consistency in the response to SRIs. Although the SRIs are effective in most studies, there are also studies in which they demonstrate no notable efficacy in relieving the symptoms of ICDs.[30]

In clinical practice, some patients seem to respond at first to SRIs but then lose that response. Additionally, while SRIs seem to be the only effective monotherapy for OCD, other classes of medication (e.g., mood stabilizers and opioid antagonists) seem to be effective in ICDs. Therefore, the inconsistency in the findings on pharmacologic treatment of IC-IUD is similar to the results found for other ICDs and may be due to the complexity of ICDs, which is not yet well understood.

CONCLUSION

Even though not formally considered an autonomous psychiatric disorder, IC-IUD has many features that would support its future inclusion in a classification system. Evidence presented to date regarding its phenomenology, epidemiology, comorbidity, and treatment response should encourage further systematic research on this condition in order to obtain a more precise understanding of its clinical features. The present study suggests that SRIs such as escitalopram may be helpful in patients suffering from IC-IUD and that further controlled studies are warranted to confirm this hypothesis. It is important for additional research to be done not only to explore the efficacy of escitalopram and other SRIs in IC-IUD, but to look at possible mediators and moderators of response.

Drug name: escitalopram (Lexapro and others).

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