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Longitudinal course of pharmacotherapy in obsessive–compulsive disorder

Jon E. Grant^a, Maria C. Mancebo^b, Eric Weinhandl^c, Brian L. Odlaug^{a,d}, Jane L. Eisen^b, and Steven A. Rasmussen^b

^aDepartment of Psychiatry & Behavioral Neuroscience, University of Chicago, Chicago, Illinois

^bDepartment of Psychiatry and Human Behavior, Butler Hospital, Brown Medical School,

Providence, Rhode Island ^cChronic Disease Research Group, Minneapolis Medical Research

Foundation, Minneapolis, Minnesota ^dDepartment of Public Health, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark

Abstract

Background—Although data fully support the use of serotonin reuptake inhibitors (SRIs) in the treatment of obsessive–compulsive disorder (OCD), investigations on pharmacotherapy discontinuation during the course of OCD are lacking. This 5-year prospective study sought to better understand the long-term course of SRI utilization among individuals with OCD.

Methods—A total of 252 adult outpatients with *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. OCD, treated with medication in the community, were examined for discontinuation and resumption of SRIs. Data on weekly OCD symptoms, medications, and dosage changes were obtained annually using the Longitudinal Interval Follow-up Evaluation.

Results—During the 5-year follow-up period, 151 patients had at least one trial of an SRI for 12 weeks or more. A total of 110 patients (43.7%) discontinued their medication (i.e. ceased taking medication for 4 weeks) at least once during the follow-up period. In patients symptomatic at the time of discontinuation, the cumulative incidence of worsening of OCD after SRI discontinuation was 9.8%, whereas in patients in partial or full remission at the time of discontinuation, the corresponding cumulative incidence was 33.3%. Among patients with worsening of OCD upon SRI discontinuation, the median time to worsening was 39 weeks.

Conclusion—This first longitudinal study on the use of SRIs in OCD found that patients who had achieved partial or full remission on SRIs were less likely to discontinue medication, and the cumulative incidence of worsening of OCD after discontinuation was negatively associated with OCD severity at the time of SRI discontinuation.

Keywords

discontinuation; obsessive–compulsive disorder; pharmacotherapy; serotonin reuptake inhibitor

Introduction

Although obsessive-compulsive disorder (OCD) is a disabling psychiatric disorder, treatment studies (Bloch *et al.*, 2010) and long-term naturalistic studies (Mancebo *et al.*, 2006) have demonstrated the efficacy of serotonin reuptake inhibitors (SRIs) in its treatment. In a previous report on patients enrolled in the Brown Longitudinal Obsessive Compulsive Study (BLOCS), a prospective follow-up study on the course of OCD in a representative clinical sample (receiving naturalistic treatments), we found that 62% of patients ($n=182$) reported positive response from recommended doses of SRIs (Mancebo *et al.*, 2006). This study is consistent with another long-term naturalistic study on OCD that found that 76% of patients ($n=57$) had a favorable outcome on SRI treatment (Reddy *et al.*, 2005).

Practice guideline recommendations for OCD suggest that most patients will require lifetime treatment. These guidelines, however, are not evidence based, and there is actually little research concerning the time period for which OCD patients need SRIs or what happens when patients discontinue medication. The few controlled relapse studies that are available have not enrolled or even followed patients beyond 2 years of treatment. Further, most studies have discontinued the drug rapidly, rather than the slow taper that is more commonly followed in clinical practice (Ravizza *et al.*, 1998). Patients who discontinue the drug and do not relapse often terminate treatment with their clinicians, leading clinicians to be more likely to treat patients who do relapse. The wish to attain full remission in patients, combined with the fact that clinicians do not continue to see patients doing well 'off drug', may result in physicians keeping some patients on SRIs longer than necessary.

The possibility that we may be overtreating some of our patients, who also tend to stay on SRIs due to the fear of relapse, is made more salient by the fact that the long-term adverse effects of SRIs have not been systematically studied prospectively in a large cohort. In this report, we examine data collected from patients who completed at least 1 year of follow-up assessments of their OCD symptoms. We hypothesized that discontinuation of SRIs would not result in a worsening of OCD symptoms in a majority of patients who had achieved partial or full remission when taking the SRI.

Methods

Patients

Individuals who met lifetime *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (DSM-IV) criteria for OCD were eligible to participate in an ongoing prospective study on the course of OCD. Study inclusion criteria for adults were: (i) primary lifetime diagnosis of DSM-IV OCD; (ii) age 19 years or older; (iii) treatment for OCD within the past 5 years; and (iv) ability to complete an in-person interview. Exclusion criteria were: (i) the presence of an organic mental disorder and (ii) inability to understand and provide voluntary, written informed consent. Patients were recruited from a variety of sources, including consecutive admissions to a hospital-based OCD specialty clinic, inpatient psychiatric units, private practice outpatient clinics (general psychiatry and cognitive behavioral therapy specialty), and community mental health centers.

Patients completed an in-person intake interview and were subsequently contacted annually for in-person or telephonic interviews. This article presents findings on the 252 patients who were treated with an SRI for at least 12 weeks both before and during the study period. The study was conducted in accordance with the Declaration of Helsinki, and the Institutional Review Boards of Brown University and Butler Hospital approved the study and the consent procedures.

Assessments

Patients were interviewed by trained research assistants and completed a semistructured clinical interview, rater-administered assessments, and self-report questionnaires. Narrative summaries of psychiatric symptoms were prepared for all patients, and DSM-IV diagnoses were assigned. Interview data were rigorously edited and reviewed by senior staff members for clinical and clerical accuracy. Raters assessed each patient using the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I; First *et al.*, 1995) and the Structured Clinical Interview for Personality Disorders (SCID-II; First *et al.*, 1997) at the intake interview.

Detailed information on demographic characteristics, clinical features, and treatments was also ascertained at intake using the Butler Hospital OCD Database, a semistructured, rater-administered questionnaire. This instrument has been used in previous phenomenological studies (see Rasmussen *et al.*, 1992).

OCD symptom severity was assessed using the Yale–Brown Obsessive Compulsive Scale (YBOCS; Goodman *et al.*, 1989a, 1989b). The YBOCS is a reliable and valid, clinician-administered interview composed of a checklist of obsessions and compulsions and a 10-item scale that assesses severity of OCD symptoms during the past week. The YBOCS was administered at intake and at annual follow-up interviews. The annual YBOCS measurements assessed OCD for the week before the interview and were not sufficiently granular for use in analyses of changes in OCD severity in precise intervals around SRI treatment discontinuation and resumption.

Annual follow-up assessments were conducted using the semistructured, reliable, and valid Longitudinal Interval Follow-up Evaluation (LIFE; Keller *et al.*, 1987). The LIFE guides patients by retrospectively examining the prior year to collect data on symptom severity of all psychiatric disorders. In addition, psychiatric status ratings (PSRs) for OCD symptom severity during each week of follow-up were recorded. The PSR for OCD uses a six-point scale with cutoff points for full DSM-IV criteria (score = 4), partial remission (score = 3 for 8 consecutive weeks), and full remission (score = 2 for 8 consecutive weeks; Eisen *et al.*, 2010). The LIFE also allows the rater to collect treatment data, including data on the use of psychotropic medications and receipt of cognitive behavioral therapy for OCD since the last interview. When possible, medication data were verified with chart records or by consultation with treatment providers.

A recommended trial for an SRI was based on the American Psychiatric Association's Practice Guidelines for the Treatment of OCD (Koran *et al.*, 2007). Recommended SRI trials included at least 12 consecutive weeks of treatment with an SRI at a dosage greater than or equal to the minimally effective dosage. To identify trials, we executed the following algorithm for each patient: (i) for each of the seven SRIs under examination, we identified each interval of continuous treatment (i.e. without any interruption); (ii) we joined discrete intervals separated by gaps in treatment no greater than 4 weeks in length; and (iii) we deleted any interval with one SRI agent that was wholly contained within a trial with another SRI agent (e.g. in the case of cessation of SRI augmentation with clomipramine). In the 5-year follow-up period, we observed a total of 406 trials. Interruptions were uncommon. Only 20 trials (4.9%) included interruptions of any length. SRI dosing was divided into low, medium, and high doses for analyses of SRI doses at intake and during follow-up. Low and high doses were defined, respectively, as less than 40 and at least 80 mg/day fluoxetine, less than 100 and greater than 200 mg/day sertraline, less than 200 and at least 300 mg/day fluvoxamine, less than 100 and greater than 250 mg/day clomipramine, less than 40 and greater than 60 mg/day paroxetine, less than 40 and at least 80 mg/day citalopram, and less than 10 and greater than 30 mg/day escitalopram.

Data analysis

For tabular summaries of demographic and clinical factors, we calculated the mean $\pm$ SD and range (from minimum to maximum). We used multivariate logistic regression models of variables to predict discontinuation of SRIs. Variables that were considered for inclusion in the models comprised the following: age, sex, race, ethnicity, relationship status, occupation, employment status, OCD-attributable disability, age at OCD onset, age at onset of minor OCD symptoms, age at onset of major OCD symptoms, age at onset of interference from major symptoms of OCD, OCD onset nature, first OCD symptom (compulsion vs. obsession), OCD duration at study intake, age at first treatment, latency between OCD onset and first treatment, duration since first treatment (at study intake), cognitive behavioral therapy receipt, cumulative psychotropic medication exposure (at study intake), psychotropic medications (at study intake), depression response to SRI use (before follow-up), OCD response to SRI use (before follow-up), Brown Assessment of Beliefs score (at study intake), Global Assessment of Functioning score (at study intake), Hamilton 25-item Depression Scale score (at study intake), Hamilton 17-item Depression Scale score (at study intake), PSR score (at study intake), YBOCS (at study intake), obsessions, cumulative obsessions, primary obsession, compulsions, cumulative compulsions, primary compulsion, trial duration, SRI agent in trial, maximum and ending SRI dose in trial, PSR at trial initiation and discontinuation, and change in PSR between trial initiation and discontinuation. To build models, we analyzed univariate associations of these variables with events of interest (i.e. discontinuation of SRI treatment, worsening of OCD, and resumption of SRI treatment). Variables with weak associations (in magnitude) or obviously nonsignificant associations ($P>0.5$) were eliminated from further consideration. Those variables that were not eliminated were jointly included in models, and variables with nonsignificant associations ($P>0.1$) in said models were dropped.

Results

Intake characteristics

Study participants included 252 male and female adults [$n=136$ (54.0%) women; mean age=40.3 $\pm$ 12.9 years (range, 21–61)] with DSM-IV OCD who completed at least 1 year of follow-up assessments and were prescribed an SRI for at least 12 weeks. Demographic and clinical variables are presented in Table 1.

A total of 229 patients (90.9%) were included in the study on SRIs and an additional 23 patients started SRI treatment during the follow-up phase of the study. Individual SRIs at the time of study entry, mean dose, and duration are presented in Table 2. Among the 229 patients who underwent prestudy treatment, 151 patients (65.9%) received an adequate trial according to the American Psychiatric Association's Practice Guidelines for the Treatment of OCD (Koran *et al.*, 2007). In this subset of 151 patients, 43 (28.5%) and 49 (32.5%) patients reported 'much improved' or 'very much improved' OCD symptoms, respectively. In contrast, in the complementary subset of 78 patients who had received an inadequate trial, 20 (25.6%) and 15 (19.2%) patients reported 'much improved' or 'very much improved' OCD symptoms, respectively.

Discontinuation of serotonin reuptake inhibitors

Of the 252 adults who had received an SRI for at least 12 weeks, 110 (43.7%) discontinued their medication at least once during the follow-up period of 5 years. Among these 110 patients, there were a total of 149 discontinuation events. Of the 110 patients who discontinued SRIs, 52 (47.3%) never restarted medication.

Significant predictors of SRI discontinuation are presented in Table 3. Older patients, those who had received cognitive behavioral therapy, those who had reported improvement from the SRI, and those who had taken the SRI for a longer period of time were all significantly less likely to discontinue medication. Conversely, those on a low dose of an SRI and those taking citalopram were significantly more likely to discontinue medication.

Of the 149 discontinuation events, 73.8% were by patients who fulfilled all criteria for OCD, 14.1% were by patients in partial remission from OCD, and 12.1% were by patients in full remission. After each discontinuation event, the patient was followed-up until a unit change of one or more in the PSR score, SRI treatment resumption, or the end of the follow-up interval.

Course of obsessive–compulsive disorder after serotonin reuptake inhibitor discontinuation

When analyzing the 141 discontinuation events [i.e. patients with a PSR of 5 or less at the time of discontinuation and excluding eight events (5.4%) associated with a PSR score of 6, which could not worsen], the mean follow-up was 55.0 (65.1) weeks. The cumulative incidence of worsening of OCD after SRI discontinuation was 16.3% (worsening OCD was defined by the earliest 1-unit change in the PSR score, relative to the PSR score at SRI discontinuation). In patients with a PSR score of 4 or more at the time of discontinuation, the cumulative incidence of worsening of OCD (as defined by at least a 1-unit increase in the PSR score) was 9.8%, whereas in patients with a PSR score of 3 or less at the time of discontinuation, the cumulative incidence of worsening was 33.3%.

In 14 patients with a PSR score of 4 or more at the time of discontinuation, after a decrease in the PSR score during the preceding trial, the cumulative incidence of worsening OCD was 28.6%. In 88 patients with a PSR score of 4 or more at the time of discontinuation, after either no change or an increase in the PSR score during the preceding trial, the cumulative incidence of worsening OCD was 6.8%. In contrast, in 25 patients with a PSR score of 3 or less at the time of discontinuation, after a decrease in the PSR score during the preceding trial, the cumulative incidence of worsening OCD was 44.0%. In 14 patients with a PSR score of 3 or less at the time of discontinuation, after either no change or an increase in the PSR score during the preceding trial, the cumulative incidence of worsening OCD was 14.3%.

The cumulative incidence of worsening OCD was not only negatively associated with OCD severity at the time of SRI discontinuation but was also positively associated with improvement in OCD severity during the trial, which ended the discontinuation. Overall, patients in remission at the time of SRI discontinuation showed low rates of OCD symptom worsening, and this was documented over an extended period of time. In the 24 trials with improvement in OCD severity (i.e. in the subset of seven trials with progression from partial remission to full remission, four trials with progression from clinical OCD to full remission, and 13 trials with progression from clinical OCD to partial remission) and ending in discontinuation of SRI treatment, the mean duration of the trials was 99.0 weeks.

Among those patients with worsening of OCD (as defined by a change from full remission to either partial remission or clinical OCD, or from partial remission to clinical OCD), the median time to worsening was 39 weeks; the first and third quartiles of time to worsening were 12 and 50 weeks, respectively.

Predictors of worsening of OCD symptoms after SRI discontinuation are presented in Table 4. Older patients, those with aggressive obsessions, and those who were even more symptomatic after their most recent SRI trial were significantly less likely to show

worsening of OCD after SRI discontinuation. Those patients with sudden OCD onset were significantly more likely to show worsening of OCD symptoms after SRI discontinuation.

After the 149 discontinuation events, the cumulative incidence of SRI resumption was 54.4% (81 SRI resumption events after the 149 discontinuation events). The mean time to SRI treatment resumption after SRI discontinuation was 32.9 (35.7) weeks. We conducted structured analyses in which we examined the distribution of PSR scores at 8 and 12 weeks before and after SRI resumption, respectively. Full remission, partial remission, and clinical OCD presented in 10, 11, and 60 resumption events at 8 weeks before SRI treatment resumption compared with 12, 7, and 60 resumption events at 8 weeks after SRI resumption (we were unable to observe PSR scores at 8 weeks after SRI resumption in two patients because resumption occurred less than 8 weeks before the end of the 5-year follow-up period). Similarly, full remission, partial remission, and clinical OCD presented in 9, 11, and 61 resumption events at 12 weeks before SRI treatment resumption compared with 11, 7, and 62 resumption events at 12 weeks after SRI resumption. Thus, the qualitative conclusion in terms of very small shifts in PSR score distribution over the peri-resumption interval was insensitive to the choice of interval half-widths of 4, 8, or 12 weeks.

Discussion

In this study, we examined the longitudinal use of SRIs in 252 individuals with OCD receiving treatment in clinical settings. To our knowledge, this is the largest and broadest sample of individuals with primary OCD that has been studied and may subsequently serve to increase the generalizability of our results. We found that a majority of patients (65.9%) received a recommended trial of an SRI (according to the American Psychiatric Association's Practice Guidelines for the Treatment of OCD; Koran *et al.*, 2007). This finding is in contrast to findings from studies on OCD in which patients have been found to be undertreated (Denys *et al.*, 2002; Blanco *et al.*, 2006). This sample included theoretically 'well-treated' patients, according to the American Psychiatric Association guidelines, who continued to have significant OCD symptoms and at least moderate psychosocial dysfunction. The primary goal of the current study, therefore, was to investigate the clinical variables associated with the discontinuation of SRIs over the course of the illness.

Our hypothesis that SRI discontinuation would result in a worsening of OCD symptoms in those who had achieved partial or full remission was generally not supported by the data. First, although approximately half of the patients stopped medication at some point, those who achieved partial or full remission were less likely to do so. In fact, only 14.1% of patients in partial remission and 12.1% in full remission stopped administration of SRIs. Among the partially or fully remitted patients who stopped SRIs, the cumulative incidence of worsening of OCD after SRI discontinuation was only 33.3%. Thus, discontinuation of SRIs was generally not associated with significant worsening of OCD symptoms. These preliminary findings suggest that after several years of treatment with an SRI, some patients may discontinue the drug and maintain improvement over several years follow-up. In fact, the findings may also suggest that perhaps some individuals are taking medications that are no longer needed for their OCD symptoms.

This study has several limitations. First, although the demographics and clinical features of our sample are consistent with those of prior OCD studies (Skoog and Skoog, 1999), the generalizability of the results is limited by the fact that patients self-selected to participate in the research study. In addition, the patients in this study were treatment-seeking patients and it is unclear how these results could be generalized to untreated individuals in the community. Second, PSR ratings may not have captured all changes in OCD severity. Third, although multiple variables were examined, changes in depression and anxiety symptoms

over the course of the SRI trials, reasons for discontinuation and resumption of an SRI, and the clinician's role in stopping and restarting an SRI were not examined, and therefore, type I error may also be present. Finally, if patients achieved remission after a considerable period of time, it may not be reasonable to conclude that 12 weeks of therapy is all that is required for some patients. An ideal design to describe the course of OCD symptoms after SRI discontinuation is to randomize responders in a double-blind design to placebo and continued SRI therapy over an extended period and then offer resumption of SRIs in those who worsen or relapse. In a naturalistic study such as this, it is hard to attribute improvement and worsening to just SRI therapy. Therefore, it may be premature to conclude that OCD patients may be receiving treatment longer than necessary.

Although this study has limitations, our sample may generalize better than that in previous OCD studies, in that the study inclusion/exclusion criteria were very broad. The study also used both self-report and inter-viewer-administered measures with strong psychometric properties and established norms.

Conclusion

Although the majority of OCD patients are prescribed SRIs, and according to our data are prescribed SRIs at an adequate dose, they remain on the same SRI at the same dose with little change over many years. In fact, a majority of patients appear to be able to discontinue SRIs without significant worsening of OCD symptoms.

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Table 1

Demographic and clinical baseline data of patients ($n=252$) who received a serotonin reuptake inhibitor for at least 12 weeks

Demographic variables	
Age (years) at intake [mean (SD)]	40.3 (12.9)
Gender [n (%)]	
Male	46.0 (116)
Female	54.0 (136)
Race [n (%)]	
White	97.6 (246)
African American	0.8 (2)
Asian	1.2 (3)
Other race	0.4 (1)
Ethnicity [n (%)]	
Nonhispanic	98.4 (248)
Hispanic	1.6 (4)
Relationship status at intake [n (%)]	
Single or cohabitating	36.9 (93)
Married	46.8 (118)
Widowed, separated, or divorced	16.3 (41)
Highest education level completed [n (%)]	
High school or less	59.5 (150)
At least some college	40.5 (102)
Employment status at intake [n (%)]	
Unemployed	41.3 (104)
Employed	58.7 (148)
OCD symptom variables	
Age of OCD onset [mean (SD)]	18.6 (9.9)
Obsessions [n (%)]	
Aggressive	69.0 (253)
Contamination	59.1 (149)
Sexual	15.5 (39)
Hoarding	28.6 (72)
Religious	29.0 (73)
Symmetry	48.4 (122)
Miscellaneous	59.1 (149)
Somatic	27.0 (68)
Compulsions [n (%)]	
Cleaning/washing	61.1 (154)
Checking	68.7 (173)
Repeating	55.2 (139)
Counting	25.8 (65)
Ordering	41.7 (105)

Demographic variables

Hoarding	27.4 (69)
Miscellaneous	60.3 (152)

OCD, obsessive-compulsive disorder.

Table 2Serotonin reuptake inhibitor use at baseline ($n=252$)

SRI at intake	%	Mean dose (SD) (mg/day)	Mean duration (SD) (weeks)
Citalopram	11.8	45.9 (25.9)	45.4 (36.1)
Escitalopram	6.6	21.2 (12.6)	17.7 (18.7)
Fluoxetine	25.8	60.5 (26.9)	318.8 (304.7)
Fluvoxamine	14.0	209.4 (87.7)	122.5 (173.0)
Paroxetine	11.4	46.3 (21.9)	132.9 (141.9)
Sertraline	20.5	155.9 (70.0)	150.2 (192.0)
Clomipramine	12.7	147.4 (60.6)	400.0 (375.9)

Table 3

Predictors of serotonin reuptake inhibitor discontinuation

	Odds ratio	95% confidence interval		<i>P</i> -value
		Lower bound	Upper bound	
Age at baseline (per 5-year increment)	0.91	0.84	0.98	0.01
CBT 11 sessions vs. <11 sessions in lifetime	0.68	0.47	0.98	0.04
OCD response to SRI use (at baseline) Improvement with treatment vs. no improvement with treatment	0.52	0.32	0.83	< 0.01
Time since initiation of current SRI trial (per 12-week increment)	0.96	0.93	0.99	0.02
Current SRI treatment				
Citalopram: yes vs. no	1.61	1.02	2.52	0.04
Fluvoxamine: yes vs. no	0.31	0.14	0.68	< 0.01
Current SRI dose				
Low vs. moderate	1.77	1.19	2.64	< 0.01
High vs. moderate	1.09	0.62	1.94	0.76

From multivariate logistic regression model.

CBT, cognitive behavioral therapy; OCD, obsessive-compulsive disorder; SRI, serotonin reuptake inhibitor.

Table 4

Predictors of worsening of obsessive–compulsive disorder after serotonin reuptake inhibitor discontinuation

	Hazards ratio	95% confidence interval		<i>P</i> -value
		Lower bound	Upper bound	
Age at baseline (per 5-year increment)	0.80	0.67	0.95	0.01
OCD onset nature				
Sudden vs. not sudden	2.13	0.92	4.94	0.08
Obsession at baseline				
Aggressive: yes vs. no	0.33	0.14	0.78	0.01
PSR score at conclusion of most recent SRI trial (per 1-point increment)	0.62	0.47	0.80	< 0.01

From multivariate Cox proportional hazards regression model, with 1 discontinuation event excluded due to unknown OCD onset nature.

OCD, obsessive–compulsive disorder; PSR, psychiatric status rating; SRI, serotonin reuptake inhibitor.