Industrial Psychiatry Journal
Publication of the Association of Industrial Psychiatry of India
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Ind Psychiatry J. 2022 Jan-Jun; 31(1): 26–30.
Published online 2022 Mar 4. doi: 10.4103/ipj.ipj_133_21: 10.4103/ipj.ipj_133_21

PMCID: PMC9255624
PMID: 35800875

Effect of sertraline and fluvoxamine on quality of life in patients with obsessive–compulsive disorder: A 12-week interventional study

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Received 2021 Jun 13; Revised 2021 Jul 11; Accepted 2021 Jul 19.

Abstract

Background:

Obsessive–compulsive disorder (OCD) is associated with poor quality of life (QoL) and functionality. Treatment leads to improvement in QoL and better functioning.

Aim:

To assess the effect of treatment with SSRIs on QoL and disability in first-episode, drug-naïve patients with OCD.

Materials and Methods:

Fifty first-episode, drug-naïve patients with a diagnosis of OCD according to the Diagnostic and Statistical Manual 5 were assessed for severity of illness (Y-BOCS), World Health Organization QoL (WHO-QoL Bref), and disability (WHODAS 2.0) at baseline and at 12 weeks after receiving treatment with either sertraline or fluvoxamine.

Results:

The scores for QoL were low and for disability were high at baseline, and the scores for WHO-QoL-Bref and WHODAS 2.0 improved significantly after 12 weeks of treatment compared to baseline. This improvement correlated with reduction in the illness severity scores on Yale-Brown Obsessive–Compulsive Scale. The responders to treatment had better QoL and lower disability compared to nonresponders.

Conclusion:

There is an impairment in QoL and disability in first-episode, drug-naïve patients with OCD, and QoL improves and disability decreases with adequate treatment with SSRIs, and this improvement correlates with improvement in the illness severity.

Keywords: Disability, obsessive–compulsive disorder, quality of life, SSRIs

The chronic and disabling course of obsessive–compulsive disorder (OCD) has detrimental effects on the quality of life (QoL), more so in the domains related to mental health.[1] As a measure of disease burden and outcome, many clinicians and researchers have studied the QoL of patients with OCD. There are many clinic-based as well as community-based studies in this area. Studies conclude that patients with OCD scored low on social and emotional domains of QoL and also lower physical well-being, compared to normal population norms.[2] Greater the severity of OCD, worse was the QOL and greater was the functional impairment.[3] The impairments in QoL were found to be associated with OCD severity, particularly severity of obsessions.[4,5] Studies assessing QoL as a measure of treatment outcome have found that baseline physical, psychological, and global QoL scores significantly improved following treatment except the social domain, but still the scores remained low in comparison to population norms.[6]

An Indian study assessed the family burden, QoL, and disability in 35 patients with OCD and compared them with 35 patients with schizophrenia. The severity of illness was rated using the Clinical Global Impression-Severity. The study concluded that severe OCD was associated with significant disability, high family burden, and poor QoL often comparable to schizophrenia.[2] Another longitudinal study assessed and compared QoL in 45 patients with OCD, 55 patients with major depressive disorder, and 150 healthy control over a period of 6 months. The study concluded that all domains of QoL are markedly affected in patients with OCD and improve with treatment. However, the changes in QoL are not necessarily correlated with corresponding changes in Yale-Brown Obsessive–Compulsive Scale (YBOCS) scores.[7]

With a commonly held notion among clinicians that clinical improvement in patients with OCD might not be transformed into improved QoL, the current study was planned to assess its validity and to assess the effect of treatment on the said parameters in first-episode, drug-naïve patients with OCD.

MATERIALS AND METHODS

Study design, selection, and description of participants

The study is a prospective, comparative, 12-week trial with intent to treat, undertaken at the Department of Psychiatry of a tertiary care teaching hospital in Northern India. For this study, initially 71 consecutive first-episode, drug-naïve patients with a diagnosis of OCD as per the Diagnostic and Statistical Manual 5[8] in the age range of 18–55 years and consenting to participate in the study were recruited from the psychiatry walk-in clinic. Written informed consent was taken from all participants. Through clinical interviewing, patients were excluded if they had comorbid depression, anxiety or any other diagnosable psychiatric illness, comorbid intellectual disability, comorbid neurological disorder, organic brain syndrome, dementia, or epilepsy, comorbid substance dependence except caffeine and nicotine, active suicidal ideas, severe medical, and surgical illnesses.

The sociodemographic and clinical details were recorded in a semistructured pro forma. YBOCS was used to rate severity of illness.[9] The Hindi version of the World Health Organization QoL-Bref Version (WHO-QOL Bref)[10] was used as a measure of generic QoL. This scale has 26 items clubbed into four domains of physical health, psychological health, social relationship, and environment. The World Health Organization Disability Assessment Schedule 2.0[11] was used to assess disability. After baseline assessment, participants were randomly assigned to sertraline and fluvoxamine drug group as per the computer-generated random number table. The starting dose of both medications was 50 mg/day. Patients were followed up at weeks 2, 4, and 6, postrecruitment, to optimize doses guided by clinical response and tolerability, to obtain maximum tolerable therapeutic dose by the end of 6 weeks, and to monitor for any adverse effects.[12] The same was continued for further 6 weeks, to achieve adequate trial duration of 12 weeks. Anxiolytics, i.e., etizolam and propranolol, were coprescribed if required and attempt was made to gradually taper and stop it by the first 6 weeks of initiation of treatment. The participants were reassessed on YBOCS, WHO-Qol-Bref, and WHODAS 2.0 at 12 weeks. Participants were further grouped into responders and nonresponders at 12 weeks, as per the standard defining criteria for response of OCD (i.e., YBOCS score reduction by 35% or more),[13] and the QoL and disability were compared between responders and nonresponders. Patients who dropped out and/or refused to continue with the study protocol were dropped from the study and managed as per the standard protocol followed in the department. The final sample for analysis consisted of 50 participants at 12 weeks (25 each in sertraline and fluvoxamine group). The average maximum tolerable therapeutic doses of sertraline and fluvoxamine were 196.00 mg and 284.00 mg/day, respectively.

Ethical approval

The study was approved by the Institutional Ethics Committee. The confidentiality of patient information was maintained, and the principles laid down by the Declaration of Helsinki[14] and the Indian Medical Council of Research[15] were adhered to. The study was registered with the Clinical Trial Registry of India (CTRI) (CTRI/2020/01/022890 [Registered

on: January 21, 2020]).

Statistical analysis

The statistical analysis was performed using the Statistical Package for the Social Science (SPSS for Windows, Version 16.0. Chicago, USA, SPSS Inc). Descriptive statistics and independent samples *t*-test were used for analyzing and comparing sociodemographic and clinical variables. Correlation between illness severity, clinical improvement, QoL, and disability was performed using the Pearson's correlation. All *P* values were two-tailed and statistical significance was set at $P < 0.05$.

RESULTS

The total study sample consisted of 50 participants. The mean age of participants was 31.90 years. Half of the participants were female (52%), married (52%), and belonged to urban background (60%). More than half (60%) of the participants had nuclear families. Most of the participants were educated till secondary level and above (62%). 36% of the participants comprised the working class. 40% of participants belonged to lower socioeconomic strata.

The mean baseline YBOCS score of 23.48 (±6.29) was suggestive of moderate illness severity in the total study sample. The mean total duration of illness was 6.64 (±5.61) years. The sociodemographic and clinical characteristics of participants in the sertraline and fluvoxamine drug group were largely comparable. There was a significant reduction in the YBOCS score of the total study sample at 12 weeks (12.88 (8.37); $P = 0.000$).

Table 1 shows the baseline and 12-week scores on WHO-QOL-Bref, WHODAS 2.0, and YBOCS for the total study sample. As shown, participants' baseline QOL scores were lower compared to scores at 12 weeks and also showed a statistically significant difference in the domains of physical health, psychological health, and social relations. The disability scores also reduced at 12 weeks compared to baseline and had a statistically significant difference in the disability domains of understanding and communication, self-care, getting along with people, life activities, and participation in society.

As shown in Table 2, there was no significant correlation between QoL, disability, and illness severity at baseline. However, at 12 weeks, A significant positive correlation was observed between reduced illness severity AND better scores on QOL in domains of physical health, psychological health, and environment. Similarly, reduced illness severity had a significant positive correlation with reduced disability scores in the domains of understanding and communication, getting around, self-care, getting along with people, life activities, and participation in society.

On comparing the QOL and disability scores among responders and nonresponders, it was seen that there was a significant difference among responders and nonresponders with respect to the two parameters. The responders have significantly better QoL and significantly lower disability as compared to nonresponders at 12 weeks of treatment as shown in Table 3.

Correlation coefficient matrix between WHODAS 2.0 and WHO-QOL-Bref revealed that WHODAS 2.0 scores were found to be inversely correlated with the WHO-QOL-Bref scores, such that higher the disability, lower was the QoL as shown in Table 4.

DISCUSSION

QoL is considered to be an important outcome parameter in various psychiatric illnesses, including OCD.[16] The aim of the current research was to study the effect of treatment with SSRIs on QoL and disability of first-episode, drug-naïve patients with OCD. The findings of the index study support the findings from literature, both Indian and Western that there is substantially decreased QoL and increased disability in patients with OCD across various domains.[2,5,7,16,17] The findings of lower QoL in the domains of physical health, psychological health, and social are also in line with findings in Indian as well as Western literature.[2,3,7,16] There was a significant reduction in the severity of illness, depicted through reduction in mean YBOCS scores, with the 12-week treatment with SSRIs, which is in concordance with various meta-analytic studies which prove the efficacy of selective serotonin reuptake inhibitors in the treatment of OCD.[17,18,19,20]

Contrary to what is commonly thought of and results of previous research show, the results of our study did not flag significant correlations at baseline between severity of illness and the QoL of the participants as well as the disability scores.[3,4] The probable explanation for such finding might be the incident inclusion of majority of patients with moderate severity of illness and significant contribution of various sociodemographic factors, assessment of which is not in scope

of the current study and exclusion of patients with comorbid depression and anxiety which are thought to be larger contributors toward poorer QoL.[6] In various studies done earlier, it is reported that inclusion of patients with comorbid depression and other anxiety disorders significantly correlates with baseline severity of illness and QoL. Thus, the exclusion criteria employed in the current study might have led to the findings of no significant correlations between baseline severity of illness and QoL.[2,16] However, the findings suggest that adequate treatment with SSRIs reduces symptoms severity and disability as well as improves QoL.

Although the illness severity might not have shown to have a direct contribution to impairments in QoL and increased disability, the clinical improvement leads to definite improvement in QoL and thereof decreased disability. This finding is well supported by previous research.[6,21]

The index study also reports that there is a significant difference between responders and non-responders on improvement in QoL and reduction is disability scores at 12 weeks. It clearly indicates that there is a strong association among YBOCS score, WHO-QOL-Bref, and WHODAS 2.0 at the end of the study, which is contrary to the earlier study by Srivastava *et al*.,[7] but supports the findings of Moritz *et al*.[16] in reporting higher QoL improvement in treatment responders than non-responders, suggesting that reduction in illness severity, improvement in symptomatology leads to alleviation of patients' daily life burdens.

The study, thus, emphasizes that adequate treatment of patients with OCD does lead to significant improvement not only in clinical status but also the QoL and therefore decreases the disability that the patients face. The study has strengths of including only first-episode, drug-naïve patients with OCD without any psychiatric comorbidities and assessing the severity of illness at baseline along with QOL and disability and at 12 weeks post treatment, but still has limitations in the form of incidental inclusion of patients of OCD with moderate severity and shorter duration of follow-up and no control group.

CONCLUSION

The study concludes that the QoL and higher disability scores in first-episode, drug-naïve patients with OCD improve significantly with 12 weeks of treatment with fluvoxamine and sertraline along with reduction in severity on YBOCS.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Figures and Tables

Table 1

Comparison of World Health Organization-quality of life-bref, WHODAS 2.0 and Yale-Brown Obsessive-Compulsive Scale scores at baseline and 12 weeks

Instrument/domain	Mean±SD		*P*
	Baseline (*n*=50)	12 weeks (*n*=50)	
Quality of life scores on WHO-QOL-bref			
Physical health	11.32±1.18	12.26±1.35	0.000**
Psychological health	11.96±1.73	12.40±1.79	0.006*
Social relations	14.04±1.87	14.72±1.62	0.000**
Environment	14.70±1.28	14.62±1.29	0.542
Disability scores on WHODAS 2.0			
Understanding and communication	1.54±1.07	0.60±1.01	0.000**
Getting around	0.20±0.69	0.16±0.61	0.159
Self-care	1.74±2.28	0.92±1.81	0.000**
Getting along with people	1.42±1.56	0.76±1.18	0.000**
Life activities	4.12±3.33	2.64±3.08	0.000**
Participation in society	7.76±2.72	4.48±2.90	0.000**
Illness severity score			
YBOCS	23.48±6.29	12.88±8.37	0.000**

*Significant at 0.05; **Significant at 0.01 level. YBOCS – Yale-Brown Obsessive–Compulsive Scale; WHO-QOL-bref – World Health Organization-quality of life-bref; SD – Standard deviation

Table 2

Correlation between severity of illness and World Health Organization-quality of life-bref score, WHODAS 2.0 scores at baseline and 12 weeks

Instrument/domains	Baseline *t*-test (*P*)	12 weeks *t*-test (*P*)
WHO-QOL_bref		
Physical health	−0.139 (0.337)	0.610 (0.000)***
Psychological health	−0.013 (0.928)	0.548 (0.000)***
Social relations	−0.265 (0.063)	0.204 (0.156)
Environment	−0.134 (0.355)	0.411 (0.003)**
WHODAS 2.0		
Understanding and communication	0.118 (0.415)	−0.667 (0.000)***
Getting around	0.006 (0.969)	−0.279 (0.050)*
Self-care	−0.022 (0.877)	−0.404 (0.004)**
Getting along with people	−0.075 (0.606)	−0.310 (0.028)*
Life activities	0.150 (0.299)	−0.622 (0.000)***
Participation in society	−0.040 (0.785)	−0.687 (0.000)***

*Significant at 0.05; **Significant at 0.01 level; ***at 0.001. WHO-QOL-bref – World Health Organization-Quality Of Life-bref

Table 3

Comparison of World Health Organization-quality of life-bref and WHODAS 2.0 scores among responders and nonresponders at 12 weeks of treatment

WHO-QOL domain	12 weeks, mean±SD		*P*
	Responder group	Nonresponder group	
WHO-QOL bref			
Physical health	12.83±0.91	10.78±1.18	0.000***
Psychological health	13.05±1.06	10.71±2.19	0.000***
Social relations	14.97±1.48	14.07±1.85	0.079
Environment	15.00±1.09	13.64±1.27	0.000***
WHODAS 2.0			
Understanding and communication	0.19±0.40	1.64±1.33	0.000***
Getting around	0.05±0.23	0.42±1.08	0.054
Self care	0.55±0.69	1.85±3.13	0.021*
Getting along with people	0.47±0.69	1.50±1.78	0.005**
Life activities	1.52±1.25	5.50±4.41	0.000***
Participation in society	3.16±1.23	7.85±3.27	0.000***

*Significant at 0.05; **Significant at 0.01 level; ***at 0.001. WHO-QOL-bref – World Health Organization-quality of life-bref; SD – Standard deviation

Table 4

Correlation coefficient matrix among the World Health Organization-quality of life-bref and WHODAS 2.0 scores

WHO-QOL-Bref	Understanding and communication	Getting around	Self-care	Getting along with people	Life activities	Participation in society
WHODAS 2.0						
Physical health	−0.074	−0.177	0.107	−0.107	−0.191	−0.172
Psychological health	−0.054	−0.363*	−0.306*	−0.181	−0.536*	−0.149
Social relations	−0.275	−0.177	−0.212	−0.117	−0.344*	−0.150
Environment	−0.310*	−0.341*	−0.236	−0.170	−0.493*	−0.390*

*Significant at 0.05. WHO-QOL-bref – World Health Organization-quality of life-BREF