A Study of Adverse Drug Effects in Patients with Obsessive Compulsive Disorder

.

ABSTRACT

Aims: To identify and record adverse effects/adverse drug reactions in patients receiving pharmacotherapy for obsessive compulsive disorder(OCD) visiting Psychiatry Out patient department of King George's Medical University, Lucknow and to assess the causality of adverse drug reactions reported by these patients.

Study design: A prospective observational study

Place and Duration of Study :This study was conducted in the Department of Pharmacology, in collaboration with Department of Psychiatry, King George's Medical University, Lucknow between February 2023 to January 2024.

Method: Patients receiving pharmacotherapy for Obsessive Compulsive disorder were recruited into the study after satisfying inclusion and exclusion criteria and observed for Adverse drug reaction.Yale-Brown Obsessive Compulsive Scale (Y-BOCS) was used to rate the severity and type of symptoms of OCD. The UKU Side Effect Rating Scale was used for assessing the side effects of medications prescribed to OCD patients and the causality of the observed adverse effects. Quantitative data summarized as Mean and Chi-Square test used for analysis of Qualitative data.

Results: A total of 72 patients were included in the study out of which 37(51.3%) developed adverse drug reactions during the study period. Most of the adverse drug reactions occurred in 18-30 years group(62.1%) with majority in male group(54%). Psychic type adverse drug reactions were commonly observed (54%)with majority reported with fluoxetine (72.9%) and dyspepsia (24.3%) was the most commonly observed adverse drug reaction. On causality assessment, most of the adverse drug reactions belonged to possible type(75.7%). 75.7% adverse drug reactions required symptomatic treatment and remaining 24.3% resolved spontaneously.

Conclusion: This study provides a representative profile of the adverse drug reactions which can be expected in obsessive compulsive disorder patients receiving pharmacotherapy. Nearly half of the study participants experienced adverse effects.

Regular monitoring of ADRs in psychiatry OPD and educating the patients about ADR can reduce the risk and it may improve the quality of care, reduction in cost of treatment, adherence to drugs and improved outcome.

Keywords: Adverse drug reactions,Fluoxetine ,ObsessiveCompulsive disorder, Selective serotonin reuptake inhibitors, Tricyclic anti depressants , UKU, Y-BOCS

1.INTRODUCTION

"Obsessive–compulsive disorder (OCD) is a chronic, disabling disorder that is characterized by recurrent thoughts(obsessions) and rituals (compulsions)"(1). "A highly prevalent and chronic condition that is associated with substantial globaldisability" (2). OCD is the fourthmost common psychiatric illness after depression, alcohol/substance abuse,and social phobia, with a lifetime incidence of 1.6% in community surveys (3) and is considered to be the world's tenth biggest cause of disability. The World Health Organisation (WHO) estimates that roughly 1% of the worldwide population suffers from OCD (4). "OCD is represented by a diverse group of symptoms that includesintrusive thoughts, rituals,preoccupations,and compulsions. An obsession is a recurrentand intrusive thought, feeling, idea or sensation and in contrast to thiscompulsion is a conscious, standardized, recurrent behaviour such as counting, checking or avoiding" (5). "Obsessions and compulsions are time consuming, distressing andare often resisted unsuccessfully.Individuals with OCD perceives their symptoms as normal,that they were similar to other people, and that their behaviours and thoughts were part of their personality. It was only when symptoms began to markedly disrupt daily life and functioning, inaddition to causing major distress, that they realize that these were pathological orindicative of having a psychiatric problem, warranting a visit to the clinic (6). If untreated, OCD is a chronic illness with a waxing and waning ofsymptoms. Although OCD can develop at any age, the majority of cases appear in adolescence and early adulthood,with the average onset age ranging from 22 to 36 years" (7)."However, OCD can occur in youngsters as early as 2 or 3 years old. OCD affects males and women equally. However, other research 1 imply thatmen acquire OCD at a younger age than women. Furthermore, some data suggests that women may have more severe OCD symptoms than males" (8).

"Treatment of OCDinvolves various strategies including pharmacotherapy, psychotherapy , psychosurgery and neuro-modulation interventions. Selective serotonin reuptake inhibitors (SSRIs) are preferred and most common SSRIs prescribed are fluoxetine , paroxetine , citalopram , escitalopram , and sertraline. SSRIs are generally preferred over clomipramine in

treating OCD. These medications increase and regulate the concentration of serotonin in the brain"(9). "Alternatives to SSRIs include clomipramine(TCA) and serotonin and norepinephrine reuptake inhibitors. Treatment of resistantcases or adjunctive therapy includes augmentation with atypical antipsychotics, pindolol, buspirone, and glutamate-blocking agents"(10). "SSRIsare generally better toleratedthan other agents, but common side effects like nausea, vomiting, insomnia, drowsiness, headache, decreased sexdrive, and agitation occurs. Some of the less common adverse effects of SSRIs reported are extrapyramidal symptoms (EPS), serotonin syndrome, QT prolongation, rash, birth defects, hyponatremia, andcataracts" (11). "The most common side effects of clomipramine are dry mouth, sedation, dizziness, and weight gain.All of the SRIs can cause sexual problems. Clomipramine can alsocause problems with blood pressure and irregular heartbeats, so that children and adolescents and patients with preexisting heart disease who are treated withclomipramine must haveelectrocardiograms (EKGs) before beginning treatment and at regularintervals during treatment. Higher doses than listed in the package insertand a longer trial are often needed for SSRIs thancompared to other psychiatric disorders"(10). These higher doses are associated with more severe side effects. An adverse drug reaction (ADR, or adverse drugeffect) can be defined as'an appreciably harmful or unpleasant reaction resulting from an intervention related to theuse of a medicinal product; adverse effects usually predict hazard from future administration and warrant preventionor specific treatment, or alteration of the dosage regimen, or withdrawal of the product'(12). "OCD necessitates the use of drugs for extended periods, ranging from months to years. Because of the prolonged duration of treatment, it islinked with a wide spectrum of adverse drug reactions .Drugs used in OCD, particularly SSRIs like fluoxetine, are known to cause various side effects. Identifying with characterizing these ADRs is beneficial for optimizing therapy. ADRs associated with psychotropic medicines can occur evenat standarddosages used in the treatment ofacute and chronic mental problems and can lead to non-compliance andin certain cases, cessation of therapy"(13). " Inpsychiatry units, pharmacovigilance can play a critical role in identifyingADRs and alerting clinicians to the potential andcircumstances of such occurrences thus saving the patients from preventableharm. ADR monitoring aids in the development of appropriate interventional programs to manage,prevent, and minimize the risk of developing ADRs, hence lowering therapeutic costs" (14).This study is conducted with the aim to study adverse effects associated with drugs used in OCD patients for optimising drug therapy to improve patient safety with less harm.

2.METHODOLOGY

2.1 Study Design : A prospective observational study.

2.2 Study Setting: Study was conducted in the Department of Pharmacology, in collaboration with Department of Psychiatry,King George's MedicalUniversity Lucknow.The department of psychiatry has 120 general beds and six private rooms. There are two male wards, one female ward and a child & adolescent ward. Department has its own pharmacy providing essential medicines for OPD patients and patients hospitalized in the ward

2.3 Study Period : Total duration of the study was 1 year from February 2023 to January 2024 with subject participation for four weeks.

2.4AStudy Sample:

- All New/Old patients attending adult psychiatric OPD in Department of Psychiatry, King George's Medical University Lucknow, on the specified days of the week and diagnosed to be suffering from obsessive compulsive disorder by the consultant in-charge and satisfying the selection criteria for the study were included.

2.4BSample size calculation :

The sample size is calculated using the following formula suggested by Charan and Biswas (2013)1:

$n= (Z1-\alpha/2)2 *p*(1-p)/d2$

where, n: Sample size

Zα/2 : critical value of z at 95% confidence = 1.96

p: Expected proportion based on previous study= 0.22 (12)

d: Absolute error = 0.1

$n = (1.96)2 *0.22*(1-0.22)/(0.1)\ 2 = 65.92$ ~66 patients

Keeping a provision of data loss @ 10%, the proposed sample size is 72.

2.5 Selection criteria for selecting patients

2.5AInclusion Criteria

- Patients with confirmed diagnosis of obsessive compulsive disorder as per ICD -11 diagnostic criteria.
- Patients aged between 18 to 60 years.(To minimize variability in adverse drug reaction profiles, as these age groups often have different pharmacokinetics, comorbidities, and medication tolerances.)
- Patients who have not received any psychiatric medications during the last 4 weeks.

- Patients willing to give a written informed consent.

2.5BExclusion Criteria

- Patients having any major medical/surgical illness or on continuous treatment for any medical disorder.
- Patient in whom evaluation is not possible due to any reason.

2.6 Sampling Method

Consecutive sampling was done until adequate sample size was reached.The firstpatient was recruited after obtaining Ethical Committee approval

2.7Assessment tools used in the study

i. Semi-Structured Proforma for recording socio-demographic and clinical details of the patients designed for the study.

ii. Yale-Brown Obsessive Compulsive Scale (Y-BOCS): Designed to rate the severity and type of symptoms in patients with OCD and is intended for use as a semi-structured interview and language of this scale is english. It consists of a checklist of common obsessions and compulsions and a 10-item measure of symptom severity, which determines symptom severity regardless of symptom subtype. Questions 1-5 are about obsessions and 6-10 are of compulsions, each question scored from 0 to 4 depending upon severity, and added at the end for total score. Total scores on the measure range from 0 to 40, with a score of 0–7 indicating subclinical symptoms, 8–15 mild symptoms, 16–23 moderate symptoms, 24–31 severe symptoms and 32–40 extreme symptoms(21).

iii. The UKU(Udvalg for Kliniske Undersogelser**)** Side Effect Rating Scale : Used for documenting ADR and assessing the side effects of medications prescribed to OCD patients, it covers various domains of side effects, including physical, psychological, and social effects. It consists of 48 items, each assessing a specific side effect. Each item is rated on a four-point scale based on the severity of the side effect: 0 (none), 1 (mild), 2 (moderate), or 3 (severe) and the management of the observed ADRs were documented as per the consequence parameter of the UKU scaleUsed forassessing the side effects of medications prescribed to OCD patients(22).

2.8 Procedure

Patients were recruited from out-patient department of Psychiatry, King George's Medical University, on specified days of the week. Patients diagnosed to be suffering from obsessive compulsive disorder by the consultant in-charge and satisfying the selection criteria on any given day were enrolled in the study after obtaining written informed consent. On the day of

enrolment socio-demographic and clinical details including medications prescribed were recorded on semi-structured proforma. Severity of OCD was assessed by Y-BOCS on the day of the enrolment. At week 2 (±3days) and week 4 (±3days) OCD severity was assessed by Y BOCS and UKU side effect rating scale was used assess the adverse effect and its causality by the principal investigator.(Patient recruitment , data collection and assessment done by the principal investigator)

2.9 STASTISTICAL ANALYSIS

The data collected were entered into Microsoft Excel Spreadsheet and analysiswas done using Statistical Package for Social Sciences(SPSS) Version 21.0.Theresults are represented in proportions and percentages, Bar and Pie diagramsused to visualize data summary.Quantitaive data represented as mean and Chi-square test used for analysis of qualitative data. Wilcoxon signed -rank test used for assessment of significance in reduction in OCD score.

3. RESULTS AND DISCUSSION

3.1 Socio-demographic characteristics of study participants

This prospective observational research included 72 participants (43 males and 29 females) across various age ranges. The majority of participants 42 (58.3%) were between the ages of 18 and 30, showing a significant representation of young people. The socio-demographic characteristics of study participants are summarisedin Table 1.

Table 1: Socio-demographic characteristics of study participants

Socio-demographic	Category	Number (%)
Age(yrs)	18-30 yrs 31-40 yrs 41-50 yrs 51-60 yrs	42(58.3%) 11(15.3%) 14(19.4%) 5(6.9%)
Sex	Males Females	43(59.7%) 29(40.3%)
Domicile	Rural Urban	7(9.7%) 65(90.3%)

Family type	Joint Nuclear	6(8.3%) 66(91.7%)
Marital status	Married Unmarried	48(66.7%) 24(33.3%)
Education	Graduate Intermediate Highschool Illiterate	16(22.8%) 27(37.5%) 20(27.7%) 9(12.5%)
Occupation	Student Government job Private job Housewife Unemployed	27(37.5%) 5(6.9%) 10(13.8%) 22(30.5%) 8(11.1%)

3.2 Drugs prescribed in OCD patients

All 72 study participants received selective serotonin reuptake inhibitors (SSRIs) as the first line drug. SSRIs prescribed in study participants are summarized inTable 2. As an add on therapy to SSRIs, 15 (20.83%) patients received tricyclic antidepressants, 42(58.3%) received benzodiazepines and 13(11.1%) were prescribed atypical antipsychotics.

Table 2: SSRIs prescribed in study participants

SSRIs	Number of patients prescribed	% of patients prescribed
Escitalopram	8	11.1
Fluoxetine	55	76.3
Paroxetine	2	2.8
Sertraline	7	9.7
Total	**72**	**100.0**

Add on drugs to SSRIs :

1 . Tricyclic antidepressants -Among the tricyclic antidepressants clomipramine was the sole medication utilized in 15 cases accounting for the entire percentage.

2. Benzodiazepines: Among the study participants, 42(58.33%) were prescribed benzodiazepines as add on therapy, while 30(41.67%) did not receive any. Clonazepam was

prescribed to 27(64.2%) etizolam to 11(26.1%) patients, while alprazolam and lorazepam were each prescribed to 2(4.7%) patients.

3. Atypical antipsychotics ; Within the prescribed group, aripiprazole was the most commonly administered atypical antipsychotic, prescribed to 5(38.4%) patients. Risperidone followed with a prescription rate of 30.7%, while olanzapine was prescribed to 3(23%) patients. A smaller proportion of patients received quetiapine fumarate, accounting for 13% of the prescribed group.

3.3 Assessment of OCD severity by Y-BOCS severity score

Patients disease severity of OCD was assessed during the study period for the effectiveness of pharmacotherapy .

Table :3Y-BOCS OCD severity score

Day 0	Week 2	Week 4	Mean decreased in scores (Day 0 to week 4)	% decreased in scores (Day 0 to week 4)	Z value	p-value
23.17±3.88	20.92±3.24	16.24±2.96	6.93	42.67%	-7.452	<0.001

Wilcoxon signed -rank test used

Comparisons from the day 0 to week 4 showed differences in Y-BOCS OCD SCORE, with mean differences of 6.93 and % decreased in scores (Day 0 to week 4) was 42.67%, exhibited significant alterations in Y-BOCS OCD score ($Z = -7.452$, $p = <0.001$), emphasizing varied patterns of change across different time points.

3.4Adverse effects /ADR observed during the study

During the trial period,37(51.3%) study participants experienced adverse effects or adverse drug reactions (ADR). The evidence from the literature suggests that the incidence of ADRs in psychiatric OPDs in India varies from 6.41% to 41.9% [15-17]. The disparity in the incidence rate reported from different studies might be due to variable study duration and reporting

culture. Studies using the spontaneous reporting method generally detect lower incidences of ADRs. Higher percentage of ADR in this study was due to active intervention in reporting and follow up.

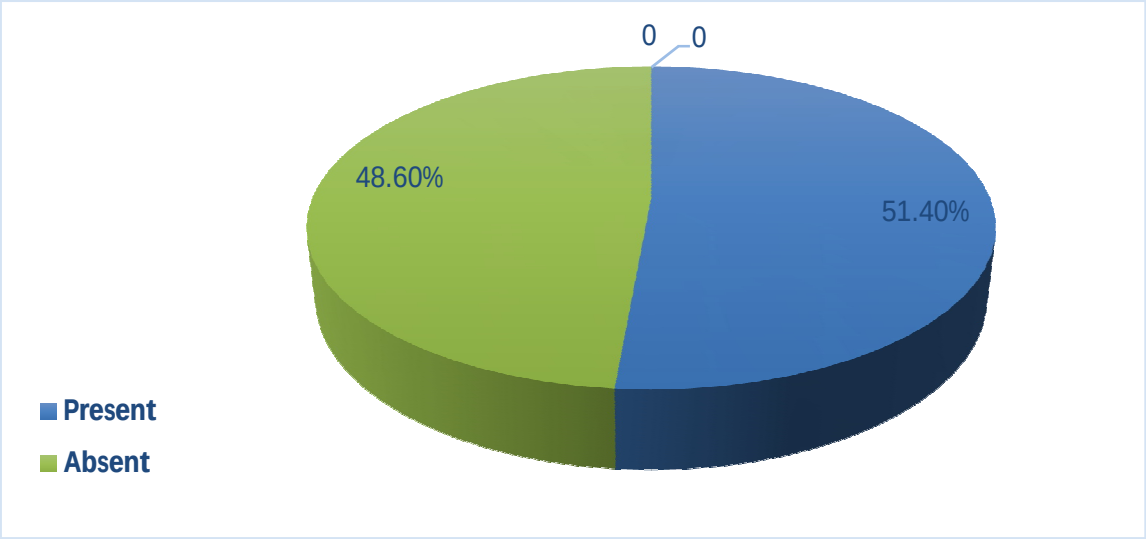

Figure 1: Adverse effects /ADR observed during the study

3.5 Age wise distribution of ADR

Among the 37 ADRs, 23(62.1%) occurred in 18-30 years group, 8 (21.6%) belonged to 31-40 age group and 3(8.1%) each in 41-50 and 51-60 age bracket. Table 3 summarizes the age wise distribution of ADR.(Table 4)

Table 4: Age wise distribution of ADR

Age(years)	Number of ADR	% of ADR
18-30	23	62.16
31-40	8	21.62
41-50	3	8.1
50-60	3	8.1
Total	37	100

3.6 Gender wise distribution of ADR

Among the 37 ADRs observed 20(54%) occurred in male group, and17(46%)

in females. (Table5)

Table 5: Gender wise distribution of ADR

Gender	Number of ADR	% of ADR
Male	20	54
Female	17	46
Total	37	100

3.7 Spectrum of Adverse Drug Reactions According to UKU-SERS

According to the UKU side effect rating scale , psychic ADRs constituted 54% of the total ADR observed as these drugs act on CNS. Similar to this study, Gawali et al.2017 found the most common organ system affected by ADRs to be CNS [15]. Psychic ADR is followed by, others type(24.3%), neurologic(10.8%) and autonomic(10.8%). Among the psychic ADRs decreased/troubled sleep was most commonly reported followed by restlessness, anxiety and sedation. Ambwani et al.2021 reported sedation as the most common ADR [18].

Among the neurological ADR tremors were reported commonly followed by headache. Mathew et al 2020 also reported tremor as the most common neurological ADR[22]. Nausea was the ADR reported in autonomic category and dyspepsia in others category. (Table 6& Figure 2)

Table 6-Adverse Drug Reactions According to UKU-SERS

Type of ADR	Number of ADR(%)	ADR(number)
Psychic ADR	20(54%)	Decreased/trouble sleep(7) Sedation(2) Restlessness(5) Anxiety(6)
Neurologic ADR	4(10.8%)	Tremors(3) Headache(1)
Autonomic ADR	4(10.8%)	Nausea(4)
Others	9(24.3%)	Dyspepsia(9)

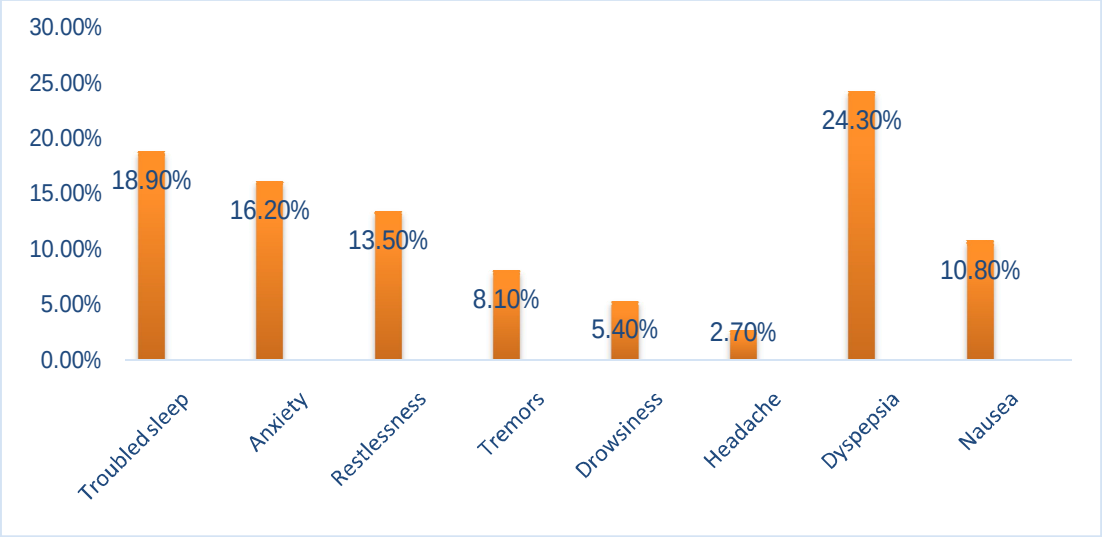

Figure 2: **spectrum of ADRs observed among study participants**

3.8Drugsresponsiblefor adverse drug reactions among study participants

In the present study, fluoxetine(72.9%) was the most common drug causing ADRs, followed by sertraline (10.8%), clomipramine (10.8%), paroxetine (5.4%), etizolam (5.4%), and escitalopram (2.7%). Sankhi et al. 2020 also showed that SSRIs were the most common drug group causing most of the ADRs [24].(Table7)

Table 7: The suspected drugs causing adverse drug reactions (ADRs)

Suspected drug	Number of ADR(%)	ADR(n)
Fluoxetine	27(72.9)	Decreased/troubled sleep(5) Anxiety(4) Restlessness(5) Drowsiness(1) Headache(1) Nausea(1) Dyspepsia(7)
Paroxetine	2(5.4%)	Decreased sleep(1) Anxiety(1)
Sertraline	1(2.7%)	Decreased sleep
Escitalopram	1(2.7%)	Dyspepsia
Clomipramine	4(10.8%)	Anxiety(1) Tremors(1) Nausea(1) Dyspepsia(1)

Etizolam	2(5.4%)	Tremors(1) Anxiety(1)

3.9 Causality assessment of the observed adverse drug reactions

Causality assessment using the UKU side effect rating scale showed that 75.7% of ADRs were of “possible” type and remaining 24.3% probable type. This observation is supported by previous studies [17, 18, 20]. Sridhar et al, study found more possible (45.5%) causal relationship followed by probable (34.9%) [13]. Above findings suggest possible relationship is most common which could be explained by usage of more than one drug or other alternative cause may be responsible for ADR. (Figure 3)

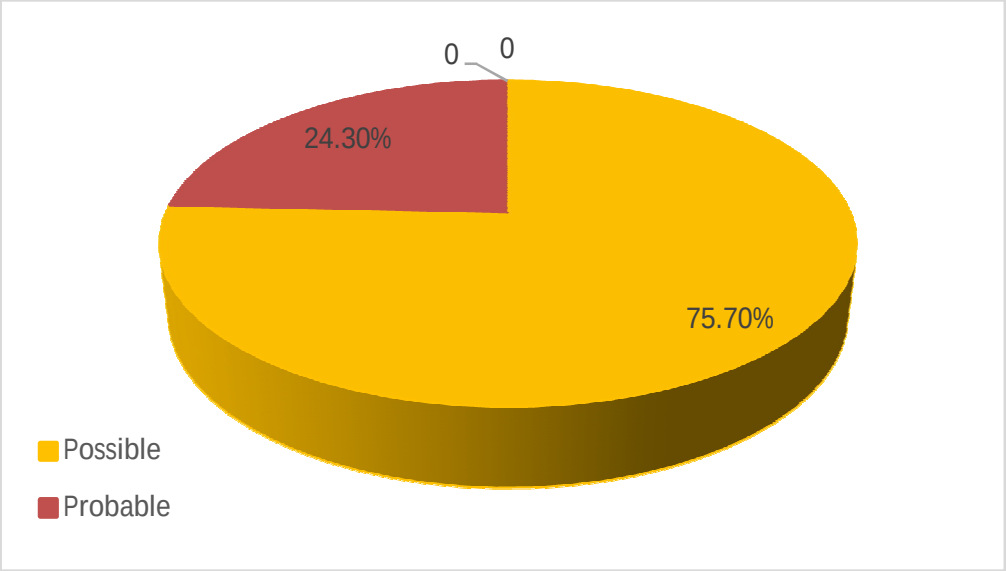

Figure 3 : Causality of observed ADRs by UKU scale

3.10Degree/consequence of ADR according to UKU scale

The consequence of the observed ADR were assessed by UKU side effect rating scale In the present study28(75.7%) belonged to degree 2 as they required symptomatic treatment and remaining 9(24.3%) into degree 1 as they not required reduction in dose or change in drug.(Table 8)

Table 8: Degree/consequence of ADR according to UKU scale

Degree	Number of ADR(N-37)	% of ADR
Degree 0	0	0
Degree 1	9	24.3
Degree 2	28	75.7
Degree 3	0	0

3.11Limitations of the study

The limitation of this study was its short duration. As the study was limited to out patient department of a single hospital and may not be representative of the rest of India. Transient and mild ADRs can be missed by the patients. Another limitation was that most ADRs were reported by doctors while other healthcare professionals were less involved

4. CONCLUSION

This study provides a representative profile of the ADRs which can be expected in OCD patients receiving pharmacotherapy.Drugs used in OCD are known to cause various side effects. ADRs associated with psychotropic medicines can occur even at standard dosages used in the treatment of acute and chronic mental problems and can lead to non-compliance and in certain casescessation of therapy. Identifying with characterizing these ADRs is beneficial for optimizing therapy. Regular monitoring of ADRs in psychiatry OPD and educating the patients about ADR can reduce the risk and it may improve the quality of care, reduction in cost of treatment, adherence to drugs and improved outcome.

Ethical Approval and consent

The research protocol was approved by Institutional Ethics Committee of King George's Medical University (KGMU), Lucknow. (vide letter number : XVI-PGTSC-IIA/P57)
Written informed consent was obtained from all the study participants.

CONFLICT OF INTEREST

There are no conflicts of interest

Author's contributions

The study was conceptualised and designed by the 2nd and 3rd author. The entire study was carried out under the supervision of 2nd , 3rd and 4th author. Data aquisition was done from psychiatry OPD by 1st author under the supervision of 2nd and 3rd author. The analysis and interpretation of data was done under the supervision of 2nd , 3rd and 4th author. Critical analysis of the work was done by the chief supervisor (2nd author) and co-supervisors (3rd and 4th author). The first draft of the manuscript was prepared by 1st author under the guidance of 2nd author. The manuscript was read and approved by all the authors. All the authors have consented for 2nd author to be the corresponding author.

DISCLAIMER

Author(s) hereby declare that NO generative AI technologies such as Large models(ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript

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