IJPSR (2026), Volume 17, Issue 2 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 15 August 2025; received in revised form, 22 September 2025; accepted, 26 October 2025; published 01 February 2026

A STUDY OF ADVERSE EVENTS OF PSYCHOTROPIC MEDICATIONS ON PATIENTS ADMITTED IN PSYCHIATRY WARD - A NATURALISTIC STUDY

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Keywords:

Psychotropics, side effects, Adverse events, Antipsychotics, Antidepressants

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ABSTRACT: Background: Psychiatric disorders requiring chronic use of psychotropic drugs can cause a wide range of potential adverse effects that can have life-threatening outcomes if not detected and treated on time. This study is aimed towards monitoring and assessing Adverse Drug Events caused by psychotropic drugs. **Methods:** A prospective observational study was done among 100 patients in Psychiatry Indoor Patients Department from January 2019 to August 2020 using convenient consecutive consenting samples to perform the tests. **Results:** The study included 100 psychiatric patients, majority suffering from schizophrenia, followed by bipolar mood disorder, major depressive disorder and obsessive-compulsive disorder. Among antipsychotics, maximum side effects were seen in patients who were on haloperidol and least in patients on olanzapine. Extrapyramidal reactions were most common with haloperidol. Clozapine caused the most sedation and hypersalivation. Among SSRIs, escitalopram had the highest side effects, including the most sexual side effects among all antidepressants. Valproate caused the most side effects, including confusion and more weight gain, tremor, and nausea than lithium. **Conclusion:** Haloperidol and risperidone caused extrapyramidal symptoms; SSRIs/TCAs led to autonomic effects; and metabolic side effects were common with second-generation antipsychotics, SSRIs, TCAs, and SNRIs. Though statistically significant, these effects lacked clinical relevance.

INTRODUCTION: Antidepressants, anti-psychotics, and mood stabilizers make up a significant portion of commonly prescribed psychotropic medications. Each class is associated with its own profile of adverse effects.

QUICK RESPONSE CODE

DOI:
10.13040/IJPSR.0975-8232.17(2).654-59

This article can be accessed online on
www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.17(2).654-59

Selective serotonin reuptake inhibitors (SSRIs) are frequently linked to symptoms such as headache, sedation, insomnia, nausea, sexual dysfunction, and hyponatremia [1].

Tricyclic antidepressants (TCAs) often lead to side effects like dry mouth, constipation, sedation, orthostatic hypotension, and cardiac arrhythmias [2]. Mirtazapine is known for causing weight gain and sedation [3]. First-generation antipsychotics (FGAs) are commonly associated with extrapyramidal side effects [4]. Antipsychotic medications, in general,

have been implicated in the development of obesity and metabolic syndrome, both of which increase the risk of cardiovascular disease and type 2 diabetes contributing factors to the reduced life expectancy observed in this patient population [5, 6]. Among mood stabilizers, lithium is notable for potential side effects such as increased urine output, hypothyroidism, hyperparathyroidism, tremors, cognitive slowing, and elevated serum calcium levels [7].

These side effects can have serious outcomes if not detected and treated on time. As a tertiary care centre and the indoor unit, we routinely prescribe different classes of psychotropic medications to our patients. Therefore, the present study was undertaken to investigate the frequency and types of adverse events reported in indoor patients receiving psychotropic medications and to study the correlation of these side effects with various demographic and phenomenological factors.

METHODS: A prospective observational study was done among 100 patients in Psychiatry Indoor Patients Department from January 2019 to August 2020 using convenient consecutive consenting samples to perform the tests.

The study was carried out after obtaining Institutional Ethics committee approval (IEC/928/18) and taking written informed consent from the participants. 100 patients above 18 years admitted in psychiatry ward and newly started on psychotropics were included. Also those patients who had stopped medications for more than 3 months and were restarted medications were also included. Those patients who did not have reliable informant, or discharged before 7 days and having medical comorbidities were excluded.

Semi-structure proforma was used to collect demographic and phenomenological details and also to assess the side effects patients had with use of psychotropic medications. Details regarding side effects were recorded at 7th day of admission and then every 7 days till discharge. Data collected was entered in excel sheet and subjected to analysis using computerized software.

RESULTS: Table 1 describes the demographic details of study population. Diagnosis of these patients was Schizophrenia and related disorders in 35% followed by bipolar mood disorder in 33%. 21% of them suffered from Major Depressive Disorder and 11% had Obsessive and Compulsive Disorder.

In our study, the mean age of patients was 32.39 years with a standard deviation of 6.70 years. The gender distribution revealed a slight male predominance with 55% males as opposed to 45% females. Our study assessed the effect of 15 medications, distributed among antidepressants, antipsychotics, and mood stabilizers.

TABLE 1: DEMOGRAPHIC DETAILS OF STUDY SAMPLE

Parameter (N=100)	Mean ± SD, (Min-Max)/ N (%)	
Age (in years)	32.39 ± 6.70 (21-54)	
Gender	Male	55 (55%)
	Female	45 (45%)
Education (in years)	7.64 ± 3.32 (2 -14)	
Religion	Hindu	67 (67%)
	Non-Hindu	33 (33%)
Marital status	Married	78 (78%)
	Unmarried	20 (20%)
	Divorced	2 (2%)
Occupation	Employed	59 (59%)
	Unemployed	41

Table 2 shows that among antipsychotics haloperidol most frequently used drug (n=27) followed by olanzapine (n=25), risperidone (n=21), and clozapine (n=17).

Maximum side effects were seen in patients who were on haloperidol and least in patients on olanzapine. Extrapyramidal reactions were maximum with haloperidol. Sedation and hypersalivation was seen maximum with clozapine. Risperidone had the maximum sexual side effects. Increased appetite was seen with both risperidone and olanzapine.

TABLE 2: SIDE EFFECTS WITH ANTIPSYCHOTICS

	Haloperidol (N=27)	Risperidone (N=21)	Olanzapine (N=25)	Clozapine (N=17)
Dose given (in mg) Mean ± S.D. (Min- Max)	11.53 ± 1.33 (10-15)	4.2 ± 0.65 (3-6)	14.06 ± 0.41 (10-15)	82.65 ± 2.76 (75-100)
Side Effect (Number of Patients)				
Sedation	11	3	4	12
Extrapyramidal Reaction	40	15	7	0
Constipation	6	0	9	4
Erectile Dysfunction	4	5	0	0
Decreased Libido	0	10	0	0
Increased appetite	0	8	8	5
Increased Salivation	0	0	0	13

In our study, among SSRIs, most frequently used escitalopram (n=33), followed by paroxetine (n=11), fluoxetine (n=11) and sertraline (n=5). Amongst SSRI maximum side effects were seen with escitalopram. Sexual side effects were maximum with escitalopram amongst all antidepressants. Overall maximum side effects were with mirtazapine. Sedation ad constipation was seen maximum with mirtazapine **Table 3.**

TABLE 3: SIDE EFFECTS WITH ANTIDEPRESSANTS

	Escitalopram (N=33)	Paroxetine (N=11)	Fluoxetine (N=11)	Sertraline (N=5)	Amitriptyline (N=10)	Venlafaxine (N=10)	Mirtazapine (N=27)
Dose given (in mg) Mean ± S.D. (Min-Max)	14.21 ± 1.31 (10 - 15)	29.95 ± 2.61 (25-37.5)	47 ± 4.74 (40 - 60)	39.37 ± 6.07 (25 - 50)	62.26 ± 1.08 (50 - 75)	38.36 ± 4.47 (37.5 - 75)	33.41 ± 2.60 (22.5 - 30)
Side Effect (Number of Patients)							
Sedation	0	4	0	0	8	0	15
Nausea	6	4	5	1	3	3	0
Fatigue	0	0	0	3	0	0	0
Constipation	0	0	0	3	6	0	7
Erectile Dysfunction	10	0	0	0	0	0	0
Decreased Libido	11	6	5	4	4	7	6
Orthostatic Hypotension	0	0	0	0	0	2	0
Dryness of Mouth	0	0	0	2	5	0	8

Table 4 shows that maximum side effects were seen with valproate. Confusion was the side effect seen only in patients on valproate. Weight gain, tremor and nausea was seen more commonly with valproate than lithium. Polyuria was seen only in patients on lithium. Oxcarbazepine had side effects of headache, nausea, dizziness and diminished sexual desire.

TABLE 4: SIDE EFFECTS WITH MOOD STABILIZERS

	Valproate (N=33)	Lithium (N=33)	Oxcarbazepine (N=10)
Dose given (in mg) Mean ± S.D. (Min- Max)	510.51 ± 30.35 (400 - 600)	803.47 ± 53.3 (600-900)	541.06 ± 115.44 (450-850)
Side Effect (Number of Patients)			
Confusion	9	0	0
Tremors	15	10	0
Nausea	7	6	6
Weight Gain	17	14	0
Polyuria	0	8	0
Dizziness	0	0	4
Headache	0	0	7
Decreased Libido	0	0	2

DISCUSSION: Our study was unique in that, unlike earlier research which focused on a single diagnosis or medication group such as the studies by Hergovich *et al.,* Tham *et al.,* Demet *et al.,* and Tielens *et al.* [8], which included only patients with major depressive disorder our study encompassed a broader clinical spectrum by including individuals with multiple psychiatric diagnoses.

The broader inclusion of multiple drug classes distinguishes our study from previous research, such as that by Tham *et al.,* Demet *et al.,* and Tielens *et al* .[8], which focused on individual drugs or specific drug groups like venlafaxine, mirtazapine, and paroxetine, respectively. Notably, the dosages used in our study remained within the FDA-approved range.

Our study highlighted the incidence and nature of adverse drug events which were associated with psychotropic medication so that a correlation between the adverse drug events and the pattern of psychotropic use could be established. It was noticed that the adverse events were more pronounced from 2 weeks after starting medications. Igor Schillevoort *et al.* study revealed that patients on risperidone and olanzapine had lower risks of EPS when compared to haloperidol in the majority of subgroups with similar treatment histories [9]. These findings are consistent with our own. Patients on risperidone who had previously experienced EPS, however, did not exhibit this. Our study did not take into account EPS's prior history. In our study, erectile dysfunction was observed in 24% of patients treated with risperidone and 15% of those on haloperidol, aligning with previous findings. Bobes *et al.* reported lower sexual dysfunction rates with quetiapine (18.2%, mean dose 360.5 mg/day) compared to risperidone (43.2%, 5.3 mg/day), haloperidol (38.1%, 10.6 mg/day), and olanzapine (35.3%, 13.5 mg/day) [10]. Clozapine was associated with improved sexual function, including orgasm frequency and satisfaction, when compared to conventional antipsychotics [11]. Another study found sexual dysfunction prevalent in patients on typical neuroleptics, regardless of prolactin levels, though hyperprolactinemia appeared to be a major contributing factor, particularly in both genders [12]. 76% of clozapine-using trial participants experienced hypersalivation. 92% of subjects exhibited hypersalivation brought on by clozapine [13]. Alpha-2 antagonism, clozapine agonism at the M4 muscarinic receptor, and unopposed beta adrenoceptor activity consequent to alpha-1 and alpha-2 antagonism are some of the hypothesized causes and reduced peristalsis of the larynx [14]. The weight increase pattern we saw with antipsychotics is consistent with a research by Jan Volavka *et al.* that found that the average weight gains (in kilograms) were 4.2 for clozapine, 5.4 for olanzapine, 2.3 for risperidone, and 0.2 for haloperidol. Research indicates that H1 Blockade is the cause of metabolic adverse effects [15].

Most research have evaluated sexual dysfunction with SSRIs, however because study methods differ greatly, it is challenging to interpret the results. The tiny sample size of those studies prevented a firm conclusion; however previous research has not demonstrated substantial differences between one specific class of SSRI-related sexual dysfunction. We believe that as the sample size is larger, certain variations across SSRIs may become apparent. Of the patients taking fluoxetine, 45% experienced nausea. Additionally, it has been documented that fluoxetine reduces appetite and food intake in rats and humans in a dose-dependent manner, resulting in weight loss. It is unknown how SSRIs cause gastrointestinal side effects, but elevated serotonin levels in the brain and GIT are probably to blame.

The enterochromaffin cells of the GIT contain 90% of the body's serotonin stores, hence it is not surprising that these medications negatively impact this system. Hyper Serotonin syndromes, like those brought on by cancerous tumors, are also known to cause effects on the gastrointestinal tract, such as anorexia, nausea, vomiting, and diarrhea [16]. Paroxetine tends to be more sedating and constipating in some patients, perhaps due to its high anticholinergic activity. Grosu *et al.* recently showed a dosage association between valproate and weight gain liability in this issue of the Journal. By further quantifying dose-related risk (approximately ½ of 1% weight increase per 500 mg dose, and especially when total dosing is above 1,300 mg/d), their retrospective, naturalistic study of 215 patients with a variety of major psychiatric disorders during a year of valproate treatment adds nuance to previous studies of valproate weight gain. For males, but not for women, weight

increase was substantially correlated with the length of treatment and the dosage of valproate. Although it remained throughout the research period, the most rapid weight increase happened in the first three months [17].

Within a month of beginning treatment, valproate tremor developed, which was comparable to essential tremor. It existed while at rest and was made worse by movement or antigravity posture. Plasma valproate levels and tremor intensity did not correlate well, however tremor typically manifested at concentrations exceeding 750 mg daily. In research by B. J. Karas, this tremor was observed in 20 out of 25 individuals [18].

With rates as high as 70% in long-term patients, excessive thirst and urination (polyuria and polydipsia) are regularly shown to be among the most common side effects related with lithium. Lithium interferes with the collecting tubules' ability to produce cyclic adenosine monophosphate in response to stimulation from antidiuretic hormones, which is how it causes polyuria. As a result, the kidneys' ability to retain free water is diminished, which impairs concentration and causes urine to become too diluted [7]. About 25% of treated people have lithium tremor [19].

CONCLUSION: Extra pyramidal side effects like akathisia and dystonia were seen with use of haloperidol and risperidone. Autonomic side effects like dry mouth, constipation, orthostatic hypotension, diminished sexual desire, erectile dysfunction were seen with use of SSRIs/TCAs.

Increase salivation, sleepiness, weight gain, increased appetite, commonly occurs with second generation antipsychotics, SSRIs, TCAs and SNRIs. Although statistically significant changes were noted with use of psychotropic drugs, none had clinical manifestations hence changes were not clinically significant.

Limitations of the Study: It was carried out in a tertiary care center and hence the results cannot be generalized. Also long term follow up was not done to check for late onset side effects.

ACKNOWLEDGEMENTS: Nil

CONFLICTS OF INTEREST: Nil

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How to cite this article:
Dokhale A, Chincholkar V, Deshpande C, Shirmali H, Sastry VS and Sonavane S: A study of adverse events of psychotropic medications on patients admitted in psychiatry ward - a naturalistic study. Int J Pharm Sci & Res 2026; 17(2): 654-59. doi: 10.13040/IJPSR.0975-8232.17(2). 654-59.