

Assessment of Fluoxetine-Associated Hyponatremia in Psychiatric Outpatients: A Cross-Sectional Study

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Abstract

Background: Fluoxetine, a commonly prescribed Selective Serotonin Reuptake Inhibitor (SSRI), is associated with hyponatremia, particularly among susceptible individuals. Early recognition of this adverse effect is important because symptoms often overlap with psychiatric manifestations and may remain undetected in outpatient settings. The present study was conducted to evaluate hyponatremia among patients receiving fluoxetine therapy in a tertiary care psychiatry outpatient department.

Methods: This hospital-based cross-sectional study was conducted among 106 adult patients receiving fluoxetine therapy in the Psychiatry Outpatient Department of a tertiary care hospital. Demographic details, psychiatric diagnosis, fluoxetine dosage, duration of therapy, and clinical symptoms suggestive of hyponatremia were recorded. Serum sodium estimation was performed using an automated electrolyte analyzer. Hyponatremia was defined as serum sodium level <135 mEq/L. Statistical analysis was performed using SPSS version 25.0, and p-value <0.05 was considered statistically significant.

Results: The mean age of study participants was 44.8 ± 13.6 years, and females constituted 58.5% of the study population. Hyponatremia was observed in 19 patients, giving a prevalence of 17.9%. Mild hyponatremia was the most common subtype (63.2%). Patients with hyponatremia were significantly older (56.1 ± 11.4 vs 42.3 ± 12.7 years, $p < 0.001$), had lower body weight (53.4 ± 8.2 vs 59.9 ± 9.6 kg, $p = 0.008$), and were more commonly females (78.9%, $p = 0.046$). Shorter duration of therapy, treatment duration ≤ 6 weeks, and fluoxetine dose ≥ 40 mg/day were significantly associated with hyponatremia. Clinical symptoms such as fatigue, headache, dizziness, nausea, and confusion were significantly more common among hyponatremic patients.

Conclusion: Hyponatremia is a clinically significant adverse effect among patients receiving fluoxetine therapy, particularly during the early weeks of treatment and in elderly females with lower body weight. Routine monitoring of serum sodium levels in high-risk individuals may facilitate early detection and prevention of severe complications associated with SSRI-induced hyponatremia.

Keywords: Fluoxetine; Hyponatremia; Selective Serotonin Reuptake Inhibitors; SIADH.

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Introduction

Psychiatric illnesses such as depression, anxiety disorders, and obsessive-compulsive disorder are among the leading causes of disability worldwide and contribute significantly to impaired social, occupational, and psychological functioning [1]. Pharmacotherapy plays a central role in the management of these disorders, and Selective Serotonin Reuptake Inhibitors (SSRIs) are currently considered first-line agents because of their efficacy and relatively better safety profile

compared to older antidepressants [2]. Fluoxetine, one of the most commonly prescribed SSRIs, is widely used in psychiatric outpatient departments owing to its therapeutic effectiveness, longer half-life, and good patient compliance [3]. Despite its favourable safety profile, fluoxetine is associated with several adverse drug reactions, among which hyponatremia has emerged as an important clinical concern [3]. Hyponatremia, defined as serum sodium concentration below 135 mEq/L, is one of

the most common electrolyte disturbances encountered in clinical practice [4]. It may present with nonspecific symptoms such as nausea, weakness, headache, lethargy, dizziness, and confusion, while severe cases can result in seizures, coma, and life-threatening neurological complications [5]. In psychiatric patients, early diagnosis may be difficult because symptoms of hyponatremia often overlap with manifestations of the underlying psychiatric disorder [6].

The mechanism of SSRI-induced hyponatremia is believed to involve Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH), leading to water retention and dilutional reduction in serum sodium levels [7]. It is observed that an increased risk of hyponatremia among patients receiving SSRIs, particularly in elderly individuals, females, patients with low body weight, and those receiving concomitant medications such as diuretics [8]. It is reported the prevalence of SSRI-associated hyponatremia to range from 0.5% to 32% [9,10]. The risk is considered highest during the first few weeks after initiation of therapy [10].

Although fluoxetine is widely prescribed in routine psychiatric practice, serum electrolyte monitoring is not consistently performed in outpatient settings, especially in resource-constrained tertiary care hospitals [11]. Consequently, mild or asymptomatic cases may remain undiagnosed, potentially increasing the risk of morbidity. Hence, the present study was undertaken to evaluate hyponatremia in patients on fluoxetine therapy attending the Psychiatry Outpatient Department of a tertiary care hospital.

Materials and Methods

Study Design and Setting: The present study was a hospital-based cross-sectional observational study conducted in the Psychiatry Outpatient Department of a tertiary care teaching hospital. The study was carried out over a period of 12 months (between January 2024 to December 2024) after obtaining approval from the Institutional Ethics Committee. The study was designed to evaluate the occurrence of hyponatremia among patients receiving fluoxetine therapy and to assess its association with demographic and clinical variables.

Study Population: The study population consisted of adult patients attending the Psychiatry Outpatient Department who were receiving fluoxetine therapy for various psychiatric disorders such as depressive disorder, anxiety disorder, obsessive-compulsive disorder, and related psychiatric illnesses. Patients aged 18 years and above who had been receiving fluoxetine for a minimum duration of two weeks were included in the study after obtaining written informed consent. Patients who were unwilling to participate were excluded from the study.

Patients with conditions known to independently cause hyponatremia, such as chronic kidney disease, congestive heart failure, chronic liver disease, hypothyroidism, adrenal insufficiency, uncontrolled diabetes mellitus, malignancy, or severe systemic illness, were excluded from the study. Patients receiving medications associated with altered sodium balance, including diuretics, carbamazepine, antipsychotics known to cause SIADH, corticosteroids, or other antidepressants in combination with fluoxetine, were also excluded to minimize confounding factors. Pregnant and lactating women were additionally excluded from the study. So, 106 eligible patients attending the Psychiatry Outpatient Department during the study period were recruited using a consecutive sampling technique.

Data Collection Procedure: After obtaining informed consent, detailed demographic and clinical information was collected from all participants using a predesigned and prevalidated case record form. Data regarding age, sex, body weight, psychiatric diagnosis, duration of illness, duration and dosage of fluoxetine therapy, associated comorbidities, and concomitant medications were recorded. A detailed clinical history was obtained with particular emphasis on symptoms suggestive of hyponatremia, including nausea, headache, fatigue, weakness, dizziness, altered sensorium, confusion, muscle cramps, and seizures.

General physical examination and systemic examination were performed in all patients. Venous blood samples were collected under aseptic precautions for estimation of serum sodium levels and other relevant biochemical parameters. Serum sodium estimation was carried out in the central biochemistry laboratory of the hospital using an automated electrolyte analyzer based on the ion-selective electrode method. Hyponatremia was defined as serum sodium concentration less than 135 mEq/L. Based on serum sodium levels, hyponatremia was further categorized as mild (130–134 mEq/L), moderate (125–129 mEq/L), and severe (<125 mEq/L).

Outcome Measures: The primary outcome measure of the study was the prevalence of hyponatremia among patients receiving fluoxetine therapy. Secondary outcome measures included assessment of the association between hyponatremia and variables such as age, sex, duration of fluoxetine therapy, dosage of fluoxetine, and clinical symptoms suggestive of sodium imbalance.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) software version 25.0 (IBM Corp., Armonk, NY, USA).

Quantitative variables were expressed as mean $\pm$ standard deviation, while qualitative variables were represented as frequencies and percentages. The normality of data distribution was assessed using the Shapiro–Wilk test. Comparison of categorical variables was performed using Chi-square test or Fisher’s exact test wherever appropriate. Continuous variables were compared using independent t-test or Mann–Whitney U test based on data distribution. A p-value of less than 0.05 was considered statistically significant.

Ethical Considerations: The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Ethical clearance was obtained from the Institutional Ethics Committee before commencement of the study.

Written informed consent was obtained from all study participants after explaining the purpose and nature of the study. Confidentiality of patient information was strictly maintained throughout the study period.

Results

The present study included 106 patients receiving fluoxetine therapy in the Psychiatry Outpatient Department. The mean age of the participants was 44.8 ± 13.6 years, with the majority belonging to the 31–45 years age group (34.9%), followed by 46–60 years (30.2%). Female patients constituted 58.5% of the study population, while males accounted for 41.5%. The mean body weight was 58.7 ± 9.8 kg. The average duration of psychiatric illness was 19.4 ± 11.2 months, whereas the mean duration of fluoxetine therapy was 8.6 ± 4.1 weeks.

Most patients were receiving fluoxetine at a dose of 20 mg/day (68.9%), followed by 40 mg/day (26.4%), while only 4.7% received doses ≥ 60 mg/day. Major depressive disorder was the most common psychiatric diagnosis observed in 46.2% of patients, followed by generalized anxiety disorder (21.7%) and obsessive–compulsive disorder (17.0%) (Table 1).

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants (n=106)

Variable	Frequency (%) / Mean $\pm$ SD
Age (years)	44.8 ± 13.6
Age group	
18–30 years	21 (19.8%)
31–45 years	37 (34.9%)
46–60 years	32 (30.2%)
>60 years	16 (15.1%)
Gender	
Male	44 (41.5%)
Female	62 (58.5%)
Body weight (kg)	58.7 ± 9.8
Duration of psychiatric illness (months)	19.4 ± 11.2
Duration of fluoxetine therapy (weeks)	8.6 ± 4.1
Fluoxetine dosage	
Fluoxetine dose 20 mg/day	73 (68.9%)
Fluoxetine dose 40 mg/day	28 (26.4%)
Fluoxetine dose ≥ 60 mg/day	5 (4.7%)
Primary Psychiatric Diagnosis	
Major depressive disorder	49 (46.2%)
Generalized anxiety disorder	23 (21.7%)
Obsessive–compulsive disorder	18 (17.0%)
Mixed anxiety–depression disorder	11 (10.4%)
Panic disorder	5 (4.7%)

Among the 106 patients evaluated, hyponatremia was detected in 19 patients, yielding a prevalence of 17.9%, whereas 82.1% had normal serum sodium levels.

Among patients with hyponatremia, mild hyponatremia was the most common form, observed in 63.2% of cases, followed by moderate

hyponatremia in 26.3% and severe hyponatremia in 10.5%. The overall mean serum sodium level of the study population was 136.8 ± 4.9 mEq/L.

Patients with hyponatremia had a significantly lower mean serum sodium level (129.7 ± 3.8 mEq/L) compared to patients without hyponatremia (138.3 ± 2.4 mEq/L) (Table 2).

Table 2: Serum Sodium Status Among Patients on Fluoxetine Therapy (n=106)

Variables	Frequency (%) / Mean $\pm$ SD
Serum Sodium Status	
Normal sodium (≥ 135 mEq/L)	87 (82.1%)
Hyponatremia (<135 mEq/L)	19 (17.9%)
Severity of Hyponatremia (n=19)	
Mild (130–134 mEq/L)	12 (63.2%)
Moderate (125–129 mEq/L)	5 (26.3%)
Severe (<125 mEq/L)	2 (10.5%)
Serum sodium level (overall)	136.8 $\pm$ 4.9 mEq/L
Serum sodium in hyponatremia group	129.7 $\pm$ 3.8 mEq/L
Serum sodium in normonatremia group	138.3 $\pm$ 2.4 mEq/L

Hyponatremia was defined as serum sodium level <135 mEq/L. Severity classification included mild (130–134 mEq/L), moderate (125–129 mEq/L), and severe (<125 mEq/L) hyponatremia. Patients with hyponatremia were significantly older than those without hyponatremia (56.1 ± 11.4 vs 42.3 ± 12.7 years, $p<0.001$). Female gender was significantly associated with hyponatremia, with females constituting 78.9% of the hyponatremic group compared to 54.0% in the normonatremic group ($p=0.046$). Patients with hyponatremia also had significantly lower body weight (53.4 ± 8.2 vs 59.9 ± 9.6 kg, $p=0.008$), and age >60 years showed a strong association with hyponatremia (42.1% vs 9.2%, $p<0.001$). Regarding clinical manifestations, symptoms such as fatigue or weakness (68.4% vs 20.7%, $p<0.001$), headache (47.4% vs 16.1%, $p=0.006$), dizziness (42.1% vs 12.6%, $p=0.004$),

nausea (36.8% vs 10.3%, $p=0.007$), and confusion (21.1% vs 2.3%, $p=0.003$) were significantly more common among patients with hyponatremia. Although seizures were observed only in the hyponatremic group, the difference was not statistically significant ($p=0.179$). Patients with hyponatremia had a significantly shorter duration of fluoxetine therapy compared to patients without hyponatremia (5.2 ± 2.1 vs 9.3 ± 4.0 weeks, $p<0.001$). Higher fluoxetine dosage (≥ 40 mg/day) was significantly associated with hyponatremia (52.6% vs 26.4%, $p=0.028$). Similarly, treatment duration ≤ 6 weeks was more frequently observed in patients with hyponatremia (73.7% vs 29.9%, $p<0.001$). A previous history of hyponatremia was also significantly associated with current hyponatremia (15.8% vs 2.3%, $p=0.041$) (Table 3).

Table 3: Association of Hyponatremia with Demographic Variables, Clinical Symptoms, and Fluoxetine Therapy Parameters

Variable	Hyponatremia Present (n=19)	Hyponatremia Absent (n=87)	p-value
	Frequency (%) / Mean ± SD		
Age (years)	56.1 ± 11.4	42.3 ± 12.7	<0.001
Female gender	15 (78.9%)	47 (54.0%)	0.046
Body weight (kg)	53.4 ± 8.2	59.9 ± 9.6	0.008
Age >60 years	8 (42.1%)	8 (9.2%)	<0.001
Clinical Symptom			
Fatigue/weakness	13 (68.4%)	18 (20.7%)	<0.001
Headache	9 (47.4%)	14 (16.1%)	0.006
Dizziness	8 (42.1%)	11 (12.6%)	0.004
Nausea	7 (36.8%)	9 (10.3%)	0.007
Confusion	4 (21.1%)	2 (2.3%)	0.003
Seizures	1 (5.3%)	0	0.179
Fluoxetine therapy parameters			
Duration of therapy (weeks)	5.2 ± 2.1	9.3 ± 4.0	<0.001
Fluoxetine dose ≥40 mg/day	10 (52.6%)	23 (26.4%)	0.028
Duration ≤6 weeks	14 (73.7%)	26 (29.9%)	<0.001
Previous history of hyponatremia	3 (15.8%)	2 (2.3%)	0.041

Negative values indicate inverse correlation, while positive values indicate direct correlation. Correlation analysis demonstrated a significant negative correlation between serum sodium levels and age ($r = -0.48$, $p<0.001$), indicating lower

sodium levels with increasing age. Fluoxetine dose also showed a significant negative correlation with serum sodium levels ($r = -0.27$, $p=0.006$). In contrast, duration of fluoxetine therapy demonstrated a significant positive correlation with

serum sodium levels ($r = 0.31$, $p=0.002$), suggesting improvement in sodium levels with longer treatment duration.

Body weight similarly showed a significant positive correlation with serum sodium levels ($r = 0.29$, $p=0.004$) (Table 4).

Table 4: Correlation Between Serum Sodium Levels and Selected Variables

Variable	Correlation Coefficient (r)	p-value
Age	-0.48	<0.001
Duration of fluoxetine therapy	0.31	0.002
Fluoxetine dose	-0.27	0.006
Body weight	0.29	0.004

Correlation analysis was performed using Pearson's correlation coefficient (r).

Discussion

The present cross-sectional study evaluated the occurrence of hyponatremia among patients receiving fluoxetine therapy in a tertiary care psychiatry outpatient setting and demonstrated that hyponatremia is a clinically significant adverse effect associated with fluoxetine use. In the present study, hyponatremia was observed in 17.9% of patients receiving fluoxetine therapy. This finding is comparable to previous hospital-based studies by Balu et al., and Powle et al., that reported prevalence rates ranging from 9% to 22% among SSRI users, particularly in elderly and high-risk populations [12,13]. A study by Gheysens et al., reported that the incidence of SSRI-associated hyponatremia varied widely from 0.5% to 32% depending upon study population and diagnostic criteria [14]. Similarly, Mo et al. observed clinically significant hyponatremia in approximately 16% of elderly patients receiving SSRIs [15]. The relatively higher prevalence observed in the present study may be attributed to active biochemical screening and inclusion of asymptomatic or mildly symptomatic patients who may otherwise remain undiagnosed in routine outpatient practice [12].

In the present study, mild hyponatremia constituted the majority of cases (63.2%), whereas severe hyponatremia was comparatively uncommon. Similar findings have been reported in previous studies by Powle et al., and Balu et al., where most SSRI-associated hyponatremia cases were mild and dilutional in nature [13,14]. This observation is clinically important because mild chronic hyponatremia may remain unnoticed yet predispose patients to fatigue, cognitive dysfunction, gait instability, and increased risk of falls, particularly among elderly individuals [15]. The mean serum sodium level among hyponatremic patients in the current study was 129.7 ± 3.8 mEq/L, which was substantially lower than the normonatremic group, further supporting the clinical significance of electrolyte monitoring in patients on antidepressant therapy [16]. Age demonstrated a strong association with hyponatremia in the present study. Patients with hyponatremia were significantly older than those without hyponatremia (56.1 ± 11.4 vs

42.3 ± 12.7 years, $p<0.001$), and age >60 years was identified as an important risk factor. This finding is consistent with studies by Jun et al., and Greenblatt et al., who reported increased susceptibility to SSRI-induced hyponatremia among elderly individuals [17,18]. Age-related decline in renal concentrating capacity, impaired free water clearance, altered antidiuretic hormone regulation, reduced total body water, and increased prevalence of comorbidities may explain the higher vulnerability among older adults [17]. In addition, elderly patients often have increased sensitivity to serotonergic stimulation of antidiuretic hormone secretion, thereby predisposing them to Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH) [18].

Female gender was significantly associated with hyponatremia in the present study, with females constituting 78.9% of the hyponatremic group ($p=0.046$). Similar gender predilection has been observed in several earlier studies by Seifert et al., and Balambika et al., [19,20]. The increased risk among females may be explained by lower body mass, differences in sodium and water homeostasis, hormonal influences, and greater susceptibility to drug-induced SIADH. Furthermore, lower body weight observed among hyponatremic patients in the present study (53.4 ± 8.2 kg, $p=0.008$) supports previous evidence by Seifert et al., and Balambika et al., suggesting that reduced body mass increases the effective concentration of SSRIs and enhances antidiuretic hormone-mediated water retention [19,20].

The present study also demonstrated that hyponatremia occurred more frequently during the early phase of fluoxetine therapy. Patients with hyponatremia had a significantly shorter duration of treatment compared to normonatremic patients (5.2 ± 2.1 vs 9.3 ± 4.0 weeks, $p<0.001$), and treatment duration ≤ 6 weeks showed a strong association with hyponatremia. These findings are in agreement with previous studies by Ambwani et al., and Tomar et al., reporting that SSRI-induced hyponatremia commonly develops within the first few weeks after initiation of therapy [21,22]. Nagashima et al., similarly observed that the risk of hyponatremia is highest during the initial 2–4

weeks of SSRI administration [23]. The likely explanation is an acute serotonergic stimulation of hypothalamic antidiuretic hormone release soon after initiation of treatment, resulting in transient impairment of water excretion [24]. Interestingly, serum sodium levels showed a positive correlation with longer duration of therapy ($r=0.31$, $p=0.002$), suggesting possible physiological adaptation over time in some patients.

Higher fluoxetine dosage was significantly associated with hyponatremia in the current study, with more than half of hyponatremic patients receiving doses ≥ 40 mg/day ($p=0.028$). Serum sodium levels also demonstrated a significant negative correlation with fluoxetine dose ($r=-0.27$, $p=0.006$). These findings suggest a possible dose-dependent relationship between serotonergic activity and antidiuretic hormone secretion. Similar observations have been documented in earlier pharmacovigilance studies by Rajiv et al., and Sarkar et al., where higher SSRI exposure was associated with greater risk of sodium imbalance [25,26].

Clinical symptoms such as fatigue, headache, dizziness, nausea, and confusion were significantly more common among patients with hyponatremia. These manifestations are consistent with the pathophysiological effects of cerebral edema and neuronal swelling caused by hypotonic plasma states [27]. Although seizures were observed in only one patient and did not achieve statistical significance, the finding highlights the potential severity of untreated hyponatremia. Importantly, many symptoms observed in the present study overlap with psychiatric manifestations, which may lead to under-recognition unless serum sodium estimation is routinely performed [28].

The present study findings emphasize the importance of regular monitoring of serum sodium levels in patients receiving fluoxetine therapy, particularly among elderly females, low body weight individuals, and patients receiving higher doses during the early weeks of treatment. Early identification and prompt management of hyponatremia may help reduce morbidity and improve the safety profile of antidepressant therapy in psychiatric outpatient settings [29,30].

Limitations

The present study had certain limitations. Being a single-center cross-sectional study, causal relationship between fluoxetine therapy and hyponatremia could not be definitively established.

The relatively small sample size may limit generalizability of findings to the wider population. Serial monitoring of serum sodium levels was not performed, and long-term outcomes of hyponatremic patients could not be assessed.

Additionally, unrecognized dietary and lifestyle factors influencing sodium balance may have acted as confounding variables.

Conclusion

The present study demonstrated that hyponatremia is a relatively common adverse effect among patients receiving fluoxetine therapy, with a prevalence of 17.9%. Elderly age, female gender, lower body weight, higher fluoxetine dosage, and shorter duration of therapy were significantly associated with increased risk of hyponatremia. Most cases were mild; however, clinically significant symptoms such as fatigue, dizziness, nausea, and confusion were more frequent among affected patients. The findings highlight the importance of routine serum sodium monitoring, particularly during the initial weeks of therapy and in high-risk individuals. Early detection and timely management may help prevent serious neurological complications and improve the safety of antidepressant therapy in psychiatric outpatient settings.

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