**Assessment of Incidence, Causality, Severity, and Preventability of Suspected Adverse Drug Reactions to Antidepressant Medications in a Psychiatry Outpatient Setting of a Secondary Care Hospital**

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**Background:** Antidepressant medications are primarily used in the management of depression and various anxiety disorders. Antidepressant medications are known to cause adverse drug reactions (ADRs). Reporting ADRs can help in the rational use of medication and better patient drug management. **Objective:** The aim of this study was to monitor the incidence and nature of ADRs to antidepressant medications in a psychiatric outpatient setting of a secondary care hospital of the UAE. **Materials and Methods:** It was a cross-sectional study conducted in the psychiatric outpatient setting of a secondary care hospital. Patients attending psychiatry outpatient department and prescribed with antidepressant medications were included. All clinical side effects or ADRs noted by physician and reported by patients were documented and assessed according to causality, severity, and preventability scales. **Results:** A total of 131 patients were screened for the presence or occurrence of ADRs. During the study duration, an aggregate of 29 patients reported at least one ADR. Incidence of suspected ADR to antidepressant medications was found to be 22.1%. Most commonly documented suspected ADR was found to be weight gain in eight (18.1%) patients followed by somnolence in four (9.1%) patients. Escitalopram was the most common drug implicated with ADR in 13 (29.6%) patients followed by fluoxetine in 6 (13.6%) patients. According to World Health Organization-The Uppsala Monitoring Centre causality assessment, the predominance of the suspected ADRs was of “possible” type in 27 (61%) patients, and “mild” in severity in 40 (91%) patients, and “not preventable” in 37 (84%) patients. A statistically significant association ($P = 0.019$) was observed only between the presence of drug-interaction and the occurrence of ADR (relative risk: 0.429, confidence interval: 0.211–0.872). **Conclusion:** Most of the suspected ADRs related to antidepressants were “mild,” “predictable,” and “not preventable” in nature. Continuous monitoring may help in identifying, reducing, and preventing the risk of ADRs.

**KEYWORDS:** Adverse drug reaction, adverse drug reaction monitoring, antidepressant medications, pharmacovigilance, psychiatry

**INTRODUCTION**

Antidepressant medicines are primarily used in the management of depression and various anxiety disorders. Antidepressants are also prescribed for conditions such as sexual dysfunction, eating disorder, and others.

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impulse control disorders, enuresis, aggression, and some personality disorders.\(^1\) Although antidepressant drugs have great benefit in treating many psychiatric disorders, they are also associated with a wide range of potential adverse drug reactions (ADRs).\(^2\) Over the years, prescription patterns of antidepressant medicines have been changed. Medications such as tricyclic antidepressants (TCAs) and monoamine oxidase inhibitors (MAOIs) have been substituted with a novel class of medicinal drugs such as serotonin-norepinephrine reuptake inhibitors (SNRIs) and selective serotonin reuptake inhibitors (SSRIs), and other new antidepressants. SSRIs are known to cause fewer side effects and more tolerable pharmacological profiles, which progress to them as the most popular class of prescribed antidepressants.\(^3\)

An earlier study conducted in the same setting reported an incidence rate of 10.2% associated with psychotrophic drugs in general.\(^4\) Another study found that 26.87% of patients who took antidepressants reported ADRs,\(^5\) whereas another study reported lower rates (19.8%) of ADR.\(^6\) A prospective observational study reported higher incidence rate of antidepressant ADRs (42.39%) in a tertiary care hospital.\(^7\) Monitoring and reporting of ADRs can play a vital role in early detection of ADRs and prevent future harm to patients; improve patient safety and improve medicine information and education; and thereby enhance the quality of care, decrease in the cost of the treatment, and better adherence to prescribed medications.\(^8\)

The objective of this study was to evaluate the incidence and nature of ADRs among outpatient psychiatric receiving antidepressant drugs based on its causality, severity, preventability, and predictability.

**Materials and Methods**

This study was conducted in the psychiatric outpatient setting of a secondary care hospital in Ras Al Khaimah, UAE. This was a cross-sectional study. We prospectively screened all the patients for the presence of suspected ADRs from December 2016 to May 2017. The study protocol was reviewed and approved by both the institutional and regional research and ethic committee of Ras Al Khaimah (Protocol no. MOHP/RAK/SUBC/NO-44/2016-PG-P).

Approximately, 12–15 patients who required treatment with at least one antidepressant medication visit the psychiatry outpatient department per week. Hence, the approximate total number of patients reviewed during the study period (6 months) was 131 patients. All these patients were screened for ADRs. Patients of both the genders and all age groups fulfill the mental and behavioral diagnostic criteria for the 10th Revision of the *International Classification of Disease* (ICD-10), prescribed with at least one antidepressant medication and registered in the psychiatry outpatient setting were screened for the presence or occurrence of ADRs. Outpatients who were not managed with any antidepressant medications and admitted as inpatients and receiving antidepressants were excluded from the study.

The cases were identified by the principal investigator by attending outpatient psychiatric department clinic (two to three times per week) at the study site along with the treating psychiatrist at one clinic of the four clinics of the department of psychiatry. The required data were gathered from the patient prescriptions, patients’ electronic medical records, and/or by interviewing the patients and their family members and were documented in the ADR reporting and documentation form.

The causality assessment of suspected ADRs was performed using Naranjo and WHO-UMC (The Uppsala Monitoring Centre) probability scales.\(^9\)\(^10\)\(^11\)\(^12\) Hartwig *et al.*’s\(^13\) scale and modified Schumock and Thornton’s\(^14\) scale were used to assess the severity and preventability of suspected ADRs.

Data were analyzed by using the Statistical Package for the Social Sciences software program, version 24.0, for Windows (IBM, Armonk, New York). A paired Student’s *t* test was performed to determine the statistically significant difference in the weight of the
patients who reported weight gain to antidepressants. The predictors of suspected ADRs were identified by calculating relative risk. The different predictors tested are gender, age, number of medications, presence of comorbid conditions, and drug–drug interactions. A value of $P < 0.05$ was considered statistically significant.

**RESULTS**

Of 131 patients who visited the outpatient clinic of the study setting, 29 patients developed at least one ADR. This incidence of suspected ADRs to antidepressant medications was found to be $29/131 \times 100 = 22.1\%$.

Among the total patients screened for ADRs, 81 (62\%) were women and 50 (38\%) were men. Female predominance (21, 72.4\%) was documented over males (8, 27.6\%) in cases of suspected ADRs to different antidepressant medications.

The mean age of all the patients who experienced ADR was $38.24 \pm 14.51$ years. Patients within the age group of 20–40 years (48.27\%) presented with the highest number of ADRs followed by the patients of age group 41–60 years (34.48\%). Among the patients who experienced ADRs, 18 (62.1\%) were UAE nationals and the remaining were expatriates 11 (37.9\%).

The average number of medications per patient who developed ADR was found to be $2.06 \pm 0.98$. The mainstream of the patients who developed an ADR received 1–2 medications ($n = 20, 68.9\%$) at the time of experiencing ADR. A sum of 44 ADRs to different antidepressant medications was reported. The average number of suspected ADRs per patient was found to be $1.5 \pm 1$. The majority of the study patients (21, 72.4\%) experienced at least one ADR.

The most commonly suspected ADR was found to be weight gain in eight (18.1\%) patients followed by somnolence in four (9.1\%) patients [Table 1]. Weight gain was documented in eight patients. A statistically significant difference ($df = 7, P = 0.005$) was observed in the weight of the patients before (69.7 ± 18.1 kg) and after receiving the suspected antidepressant medications (75.7 ± 17.8 kg). Escitalopram was the most common drug responsible for ADR in 13 (29.6\%) patients followed by fluoxetine in 6 (13.6\%) [Table 2].

Higher prevalence of ADRs was documented in 11 (38\%) patients with major depressive disorder followed by generalized anxiety disorder in 7 (24.2\%) cases [Table 3]. The most commonly affected organs were central and peripheral nervous system due to ADRs in 16 (36.2\%) cases, followed by metabolic and nutritional disorders in 9 (20.4\%) [Table 4].

**Table 1: Spectrum of different adverse drug reactions and drug(s) implicated**

| Type of ADRs     | $n$ (%) | Drug(s) implicated                        |
|------------------|---------|------------------------------------------|
| Weight gain      | 8 (18.2) Escitalopram ($n = 4$), duloxetine ($n = 1$), mirtazapine ($n = 2$), and fluoxetine ($n = 1$) |
| Rash             | 1 (2.3)  Escitalopram ($n = 1$)                                   |
| Decreased appetite| 1 (2.3)  Escitalopram ($n = 1$)                                   |
| Increased irritability | 2 (4.5)  Escitalopram and mirtazapine (1 each)               |
| Headache         | 2 (4.5)  Escitalopram and agomelatine (1 each)                   |
| Flushing         | 1 (2.3)  Escitalopram ($n = 1$)                                   |
| Sedation         | 3 (6.8)  Amitriptyline ($n = 1$) and imipramine ($n = 2$)        |
| Elevated blood pressure | 2 (4.5)  Duloxetine and venlafaxine (1 each)         |
| Sexual dysfunction| 1 (2.3)  Escitalopram ($n = 1$)                                   |
| Abdominal pain   | 3 (6.8)  Escitalopram, agomelatine, and fluoxetine (1 each)      |
| Flu-like syndrome| 1 (2.3)  Mirtazapine ($n = 1$)                                   |
| Palpitation      | 1 (2.3)  Fluoxetine ($n = 1$)                                    |
| Somnolence       | 4 (9)    Fluoxetine, mirtazapine, fluvoxamine, and paroxetine (1 each) |
| Vomiting         | 1 (2.3)  Escitalopram ($n = 1$)                                   |
| Nausea           | 1 (2.3)  Escitalopram ($n = 1$)                                   |
| Excessive dreams | 3 (6.8)  Fluoxetine, venlafaxine, and paroxetine (1 each)        |
| Xerostomia       | 1 (2.3)  Clomipramine ($n = 1$)                                   |
| Tremor           | 2 (4.5)  Fluoxetine and clomipramine (1 each)                     |
| Dizziness        | 2 (4.5)  Maprotiline and imipramine (1 each)                      |
| Sweating         | 1 (2.3)  Imipramine ($n = 1$)                                    |
| Loss of weight   | 1 (2.3)  Paroxetine ($n = 1$)                                    |
| Fatigue          | 1 (2.3)  Duloxetine ($n = 1$)                                    |
| Blurred vision   | 1 (2.3)  Duloxetine ($n = 1$)                                    |

ADRs = adverse drug reactions

**Table 2: Different antidepressant drugs associated with adverse drug reactions**

| Suspected drug | $n$ (%), ($n = 44$) |
|---------------|---------------------|
| Escitalopram  | 13 (29.6)           |
| Fluoxetine    | 6 (13.6)            |
| Mirtazapine   | 5 (11.4)            |
| Duloxetine    | 4 (9.1)             |
| Imipramine    | 4 (9.1)             |
| Paroxetine    | 3 (6.8)             |
| Venlafaxine   | 2 (4.5)             |
| Agomelatine   | 2 (4.5)             |
| Clomipramine  | 2 (4.5)             |
| Fluvoxamine   | 1 (2.3)             |
| Maprotiline   | 1 (2.3)             |
| Amitriptyline | 1 (2.3)             |
The suspected ADRs belonged to categories of “possible” (37, 84%) type by Naranjo’s causality assessment, whereas the predominance of the suspected ADRs was “possible” (27, 61%) in nature by WHO-UMC causality assessment. The greater proportion of the suspected ADRs were “mild” (40, 91%) in severity. The good number of the suspected ADRs (29, 66%) was of “predictable” types. The preventability assessment shows that most of the suspected ADRs were of “not preventable” type (37, 84%) [Table 5].

In majority of the cases (21, 48%), drugs were withdrawn to manage ADRs suspected to be caused by antidepressant medication. No change of antidepressant medication was performed in 19 (43%) patients. The majority of the suspected ADRs were not treated (40, 91%), whereas 4 (9%) received symptomatic treatment. The outcome was unknown for nearly half of the suspected ADRs (20, 46%), whereas it was known for 16 (36%) cases. Approximately, 16 (36%) of the cases had no dechallenge of suspected drug and definite improvement of ADRs was observed on dechallenge in 13 (30%) cases. Rechallenge of the suspected drug was not performed for any of the cases [Table 6].

| Diagnosis | n (%) (n = 29) |
|-----------|---------------|
| Major depressive disorder | 11 (38) |
| Generalized anxiety disorder | 7 (24.2) |
| Obsessive-compulsive disorder | 2 (7) |
| Adjustment disorder with depressed mood | 2 (7) |
| Adjustment disorder with anxiety | 1 (3.4) |
| Major depressive disorder with psychotic features | 1 (3.4) |
| Post-traumatic stress disorder | 1 (3.4) |
| Social phobia | 1 (3.4) |
| Nocturnal enuresis | 1 (3.4) |
| Autistic disorder | 1 (3.4) |
| Somatization disorder | 1 (3.4) |

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| Autistic disorder | 1 (3.4) |
| Somatization disorder | 1 (3.4) |

Table 3: Psychiatric disorders associated with suspected adverse drug reactions

Table 4: Different organ systems associated with adverse drug reactions

Table 5: Causality assessment of suspected adverse drug reactions

ADR = adverse drug reactions, SOC = system-organ classification, WHO-ART = World Health Organization-adverse drug reaction

ADR = adverse drug reaction, WHO = World Health Organization
Among the probable risk factors, a statistically significant association \((P = 0.019)\) was observed only between the presence of drug interaction and the occurrence of ADR (relative risk: 0.429, confidence interval: 0.211–0.872) [Table 7].

### DISCUSSION

The primary objective of our research was to evaluate the incidence and nature of ADRs to antidepressant drugs and was limited only to patients visiting psychiatric outpatient department. The incidence of ADRs in our study was found to be 22.1%, whereas earlier study conducted in the same setting reported an incidence rate of 10.2% associated with psychotropic drugs in general.\(^6\) Earlier studies have reported ADR incidence rate varying from 19.8% to 42.39% among patients who took antidepressants.\(^3-^7\) Our observation falls within these reported ranges.

The most frequent drug associated with ADRs was escitalopram, and the most common documented ADR was weight gain. A study reported that amitriptyline, clomipramine, and mirtazapine were associated with weight gain. While in the SSRI group, escitalopram may induce weight, however, researchers of this study have reported diverse observations for paroxetine and fluoxetine.\(^15\) Few studies reported that there are several possible mechanisms for weight gain induced by antidepressant, which includes high affinity to hypothalamic histamine H1 receptors and increased serum leptin.\(^4,15,16\)

The underlying mechanisms for weight gain caused by antidepressant medication is not fully understood.

### Table 6: Outcome of suspected adverse drug reactions

| Outcome of suspected ADRs                                     | No. (% of ADR) |
|---------------------------------------------------------------|----------------|
| Management of suspected ADRs                                  |                |
| Drug withdrawal                                               | 21 (48)        |
| Dose altered                                                  | 4 (9)          |
| No change                                                     | 19 (43)        |
| Treatment of suspected ADRs                                   |                |
| Specific                                                      | 0 (0)          |
| Symptomatic                                                   | 4 (9)          |
| Nil                                                           | 40 (91)        |
| Outcome of suspected ADRs                                     |                |
| Fatal                                                         | 0 (0)          |
| Recovery                                                      | 16 (36)        |
| Continuing                                                    | 8 (18)         |
| Partial improvement                                           | 0 (0)          |
| Unknown                                                       | 20 (46)        |
| Dechallenge of suspected ADRs                                 |                |
| Unknown                                                       | 15 (34)        |
| No improvement                                                | 0 (0)          |
| Definite improvement                                          | 13 (30)        |
| No dechallenge                                                | 16 (36)        |
| Rechallenge of Suspected ADRs                                 |                |
| No occurrence                                                 | 0 (0)          |
| Recurrence of symptom                                         | 0 (0)          |
| No rechallenge                                                | 44 (100)       |

ADRs = adverse drug reactions

### Table 7: Predisposing factors for development of adverse drug reactions in the study population

| Variable                        | Category | Presence of ADR | Relative risk (95% CI) | \(P\) value |
|---------------------------------|----------|-----------------|-------------------------|-------------|
| Gender                          | Male     | 41              | 9                       | 1 (ref)     | 0.3784 |
|                                 | Female   | 61              | 20                      | 1.3717      | (0.6789–2.7715) |
| Age group (in years)            | <65      | 89              | 27                      | 1 (ref)     | 0.4123 |
|                                 | \(\geq 65\) | 13              | 2                       | 0.5728      | (0.1512–2.1700) |
|                                 | Expat    | 33              | 10                      | 1.0771      | (0.5493–2.1119) |
| Presence of comorbidity         | Present  | 55              | 12                      | 0.6743      | (0.3503–1.2978) |
|                                 | Absent   | 47              | 17                      | 1 (ref)     | 0.2381 |
| Number of medications           | <7       | 85              | 26                      | 1 (ref)     | 0.4255 |
|                                 | \(\geq 7\) | 17              | 3                       | 0.6404      | (0.2140–1.9165) |
| Presence of drug interaction    | Yes      | 58              | 9                       | 0.4299      | (0.2117–0.8727) |
|                                 | No       | 44              | 20                      | 1 (ref)     | 0.0195* |

ADR = adverse drug reaction, CI = confidence interval
*\(P < 0.05\) is considered as statistically significant
Sridhar, et al.: Adverse drug reactions to antidepressant medications

and additional studies are essential for inspecting the role of neurotransmitters and other possible factors.[15] Moreover, the treatment of drug-induced weight gain involves encouraging exercise, counseling by a dietician or switching to another antidepressant with fewer weight issues or psychotherapy.[4,17] In our study, we noticed one patient who reported loss of weight probably due to paroxetine. The treating psychiatrist noted that paroxetine is generic formulation and this may be the reason for losing weight. No standard literatures are available regarding loss of weight due to paroxetine.

A study reported that SSRIs are the most common class associated with ADRs.[7] A longitudinal, observational study conducted in the outpatient psychiatry department reported that ADRs were most commonly observed with TCAs (58.84%) and the common ADRs were agitation and insomnia.[5] Another study found that ADRs were mostly observed with TCAs followed by SSRIs.[6] Somnolence was the second ADR detected in our study. Somnolence was observed with SSRIs and mirtazapine. Sridhar et al.[6] conducted a study on psychotropic drugs in general where somnolence was a second common ADR and some of these patients were on antidepressants. Somnolence is an adverse effect of central nervous system (CNS), which can commonly cause by psychotropic medications that act on the CNS. It may continue for first few months, but usually wears off. Sleep disturbances were reported in about 25% of patients taking SSRIs in another study.[18]

The third ADR was sedation, which was noticed with TCAs. It is known that TCAs have anticholinergic and antihistaminergic effects that produce sedation. This side effect often reduces in the first few weeks after initiation of treatment, and any patients who experience minor difficulty from sedation should be counseled to allow some time before switching to another antidepressant.[17,18] Patients with insomnia may benefit from sedation and the medication should be taken before bedtime.[17] It is worth to note that in our study there were two pediatric patients who were prescribed with imipramine for nocturnal enuresis and both complained of severe sedation that their families decided to stop the treatment. The treating psychiatrist believes that it may be due to the fact that imipramine was generic preparation.

There were three reports of excessive dreams as an ADR documented in our study. Excessive dreams were associated with SSRIs and SNRIs. A small number of published studies report that the SSRIs intensify dreaming. A study performed to examine the dream effects of paroxetine and fluvoxamine reported that the subjective intensity of dreaming increased during both treatment and acute discontinuation compared with baseline.[19] Earlier studies designate a strong impact of antidepressants on dream recall and dream content. There are definite pharmacological effects of antidepressants on dream recall frequency and content. However, antidepressant effects on dreams should be studied and recognized to be used in the treatment.[20] Excessive dreams can be resolved within a few weeks and seldom lead to a change in treatment.[18]

Abdominal pain contributed to an incidence rate of 6.8% with escitalopram, agomelatine, and fluoxetine. Nausea and vomiting were noted with escitalopram each with an incident rate of 2.3%. It is known that SSRIs can cause Gastrointestinal tract upset, but this adverse effect is normally dose dependent and likely to disappear over the first few weeks of treatment.[17,21] Another study reported a higher rate of nausea with adults receiving SNRIs than adults receiving SSRIs.[21]

A study reported a small increased risk of upper gastrointestinal hemorrhage with SSRI compared with TCA.[22] It is recommended to advise the patient to administer the drug after food or in divided doses.[17]

Irritability with escitalopram and mirtazapine and headache with escitalopram and agomelatine were reported in our study. A cohort study of antidepressant monotherapy reports side effects such as headache followed by nausea in higher percentages than our study.[21] Headache tends to be lasting for a short time and recover within the first few weeks of treatment.[17] Elevated blood pressure with SNRIs was reported in our study. Although all SNRIs can increase blood pressure, this risk is greater with venlafaxine compared to duloxetine and it is dose dependent. Therefore, blood pressure should be monitored before starting SNRIs and periodically during the treatment.[17] Elevation of blood pressure with SNRIs is dose related, so it may respond to dose reduction. If not, a different antidepressant medication should be chosen.[17]

Rash, decreased appetite, flush, and sexual dysfunction all were reported with escitalopram, flu-like symptoms with mirtazapine, palpitation with fluoxetine, xerostomia with clomipramine, sweating with imipramine, and fatigue and blurred vision with duloxetine. A study found that the most frequently reported ADRs were dry mouth and diaphoresis (sweating).[7] Munoli and Patil[6] reported that the most common ADR was dry mouth. Sexual dysfunction with SSRIs occurs due to stimulation of serotonin 5-hydroxytryptamine receptors (5HT-2 & 5-HT3) receptors.[18] Patient education about side effects will enhance medication adherence and improve treatment outcome. Patients should be encouraged to report any side effect.[18]
The most common psychiatric condition associated with ADRs in this study was major depressive disorder. Almost similar findings were reported by Sridhar et al.,[4] in a study associated with psychotropic drugs in general, where they found that ADRs were more common with depression. A study on ADR monitoring of antidepressants reported that major depression was the most common disorder, 53.68% followed by anxiety 25.79%.[2]

The causality assessment findings of our study were in accordance with one study where they reported that the majority of suspected ADRs belonged to the “possible” category, according to the WHO-UMC assessment scale.[5] Munoli and Patil[6] stated that all the suspected ADRs were of mild to moderate in severity, whereas Mukherjee et al.[3] assessed that ADRs were found to be probable and mild in severity. In our study, most of the suspected ADRs were of “predictable” and “not preventable” type. Lahon et al.[23] reported that the majority of ADRs were “not preventable.” Another study of psychotropic drugs reported that the most of the documented ADRs were of “not preventable” type.[4] Iuppa et al.[24] studied pharmacist interventions to prevent ADRs in a psychiatric setting. Among medication classes responsible for ADRs, antidepressants had a lower rate (8%) but this study highlighted the role of the pharmacists where 87% of their interventions were categorized as “prevention of ADR” and 96.5% of pharmacists’ recommendations were accepted.

There are known potential predictors of ADRs such as age, gender, race, and the number of drugs received/ polypharmacy and other demographic factors; therefore, the association between these demographic factors and number of ADRs was analyzed in our study, none of the demographic factors were significant predictors of ADR.[25]

On the basis of the findings of our study, it is recommended to carry out a multicenter study involving larger population and longer study duration to identify rare and late onset ADRs and draw specific conclusions in relations to the predictors of the ADRs. In addition, our study highlights the need of continuous monitoring of ADRs in patients receiving antidepressants and provides the basis for future research in pharmacovigilance related studies in psychiatry settings.

Limitations: The main limitation of this study was a small sample size as it is a single-center study and the patients were selected randomly from a single clinic, so the sample may not represent all the psychiatric cases treated in the same setting. Another limitation was the short study duration. A longer duration may be more beneficial in identifying a wider range of ADRs. Limited options for the selections of antidepressants also limited the psychiatric choices as the study was conducted in a governmental hospital. The majority of the suspected ADRs observed in our study were of “mild” in severity as the study was conducted in an outpatient setting.

Conclusion

In conclusion, this study represents different types of suspected ADRs to antidepressants, which are encountered in a psychiatry outpatient setting in the UAE. Most of the suspected ADRs documented during the study were of milder nature, predictable, and were not preventable. In majority of the cases, drugs were withdrawn to manage ADRs suspected to be caused by antidepressant medication. Reporting ADR can help in rational use of medication and better patient drug management.

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Siddiqui RA, Shende TR. Prescription pattern of antidepressant drugs in a tertiary care centre of central India. J Cont Med A Dent 2014;2:4-6.
2. Mukherjee S, Sen S, Chatterjee SS, Era N, Ghosal M, Tripathi SK. Adverse drug reaction monitoring of antidepressants in the psychiatry out patient department at a tertiary care teaching hospital in India: a cross-sectional observational study. Eur J Psychol Educ Stud 2015;2:14-9.
3. Amuthaganesh M, Suhasinee S, Mathialagan S. Pattern of antidepressant utilization at a tertiary hospital in Malaysia. Asian J Pharm Clin Res 2009;5:43-6.
4. Sridhar SB, Al-Thamer SS, Jabbar R. Monitoring of adverse drug reactions in psychiatry outpatient department of a secondary care hospital of Ras Al Khaimah, UAE. J Basic Clin Pharm 2016;7:80-6.
5. Mishra S, Swain TR, Mohanty M. Adverse drug reaction monitoring of antidepressants in the psychiatry outpatient...
department of a tertiary care teaching hospital. J Clin Diagn Res 2013;7:1131-4.
6. Munoli S, Patil SB. Monitoring of adverse drug reactions to antidepressant drugs in a teaching hospital. Int J Basic Clin Pharmacol 2017;6:933-7.
7. Lucca JM, Madhan R, Gurumurthy P, Dushad R. A prospective observational study to evaluate safety reporting of antidepressants at a tertiary care hospital in India. Indian J Pharmaco 2014;46:543-6.
8. Zaki SA. Adverse drug reaction and causality assessment scales. Lung India 2011;28:152-3.
9. Belhekar MN, Taur SR, Munshi RP. A study of agreement between the Naranjo algorithm and WHO-UMC criteria for causality assessment of adverse drug reactions. Indian J Pharmaco 2014;46:117-20.
10. Rajkumar RP, Melvin G. Pharmacovigilance for psychiatrists: an introduction. Indian J Psychiatry 2014;56:176-81.
11. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981;30:239-45.
12. The use of the WHO-UMC system for standardized case causality assessment. Available from: http://www.WHO-UMC.org/graphics/4409.pdf. [Last accessed on 2017 Mar 18].
13. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J Hosp Pharm 1992;49:2229-32.
14. Schumock GT, Thornton J. Focusing on the preventability of adverse drug reactions. Hosp Pharm 1992;27:538.
15. Ranjbar S, Pai NB, Deng C. The association of antidepressant medication and body weight gain. Online J Health Allied Sci 2013;12:1.
16. Hinze-Selch D, Schuld A, Kraus T, Kühn M, Uhr M, Haack M, et al. Effects of antidepressants on weight and on the plasma levels of leptin, TNF-alpha and soluble TNF receptors: a longitudinal study in patients treated with amitriptyline or paroxetine. Neuropsychopharmacology 2000;23:13-9.
17. Gelenberg A, Freeman M, Markowitz J, Rosenbaum J, Thase M, Trivedi M, et al. Practice guideline for the treatment of patients with major depressive disorder. Washington, DC: American Psychiatric Association; 2010 Available from: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/mdg.pdf. [Last accessed on 2016 Oct 17].
18. Khawam EA, Laurencic G, Malone DA Jr. Effects of antidepressants: an overview. Cleve Clin J Med 2006;73:351-3, 356-61.
19. Pace-Schott EF, Gersh T, Silvestri R, Stickgold R, Salzman C, Hobson JA. SSRI suppresses dream recall frequency but increases subjective dream intensity in normal subjects. J Sleep Res 2001;10:129-42.
20. Tribl GG, Wetter TC, Schredl M. Dreaming under antidepressants: a systematic review on evidence in depressive patients and healthy volunteers. Sleep Med Rev 2013;17:133-42.
21. Anderson HD, Pace WD, Libby AM, West DR, Valuck RJ. Rates of 5 common antidepressant side effects among new adult and adolescent cases of depression: a retrospective US claims study. Clin Ther 2012;34:113-23.
22. Opatrny L, Delaney JA, Suissa S. Gastro-intestinal haemorrhage risks of selective serotonin receptor antagonist therapy: a new look. Br J Pharmaco 2008;66:76-81.
23. Lahon K, Shetty H, Paramel A, Sharma G. Adverse drug reaction monitoring of antipsychotics, antidepressants and mood stabilizers in the psychiatric outpatient unit of a teaching hospital—a retrospective study. Int J Pharma Bio Sci 2012;3:470-8.
24. Iuppa CA, Nelson LA, Elliott E, Sommi RW. Adverse drug reactions: a retrospective review of hospitalized patients at a state psychiatric hospital. Hosp Pharm 2013;48:931-5.
25. Lucca JM, Ramesh M, Ram D, Kishor M. Incidence and predictors of adverse drug reactions caused by drug-drug interactions in psychiatric patients: an empirical study. Trop J Med Res 2016;19:29-35.