Original Article

Monitoring of adverse drug reactions in psychiatry outpatient department of a Secondary Care Hospital of Ras Al Khaimah, UAE

Abstract

Background: Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality, resulting in increased healthcare cost. Association of psychotropic medications with ADRs is common. Pharmacovigilance can play a vital role in alerting the healthcare providers from the possible ADRs and thus protecting the patients receiving psychotropic medications.

Aim: To monitor and report the incidence and nature of ADRs in psychiatry outpatient department (OPD).

Materials and Methods: A prospective observational study was carried out in the psychiatry OPD. All the patients attending psychiatry outpatient and satisfying the inclusion criteria were monitored for ADRs. The causality, severity and preventability assessment of documented ADRs was done. Chi-square test was done to identify the association between ADRs and sociodemographic, disease and treatment-related variables. Paired Student's *t*-test was carried out to compare the significance difference in the weight of the patients who reported weight gain to psychotropic medications.

Results: The incidence rate of ADR was found to be 10.2%. A total of 112 ADRs were documented. Weight gain 18 (16.07%) followed by somnolence 8 (7.14%) was the most commonly reported ADR. Atypical antipsychotics 37 (33.0%) were the most common class of psychotropic drugs implicated in ADRs. Escitalopram 16 (14.28%) followed by quetiapine 14 (12.5%) were associated with a maximum number of ADRs. No significant association ($P > 0.05$) documented between demographic and treatment-related variables with number of ADRs.

Conclusion: Study revealed a moderate incidence of ADRs in patients attending the psychiatry OPD. Majority of the ADRs reported during the study were mild in nature and not preventable type.

Key words:
Adverse drug reaction, adverse drug reaction monitoring, pharmacovigilance, psychiatry outpatients, psychotropic medications

Introduction

Adverse drug reactions (ADRs) are known to be the significant cause of morbidity and mortality both inpatients and outpatients settings.[1] The overall incidence of serious and fatal ADRs among hospitalized patients was found to be 6.7% and 0.32%, respectively.[2] While in outpatient settings, the incidence of ADRs ranges from 5% to 35%.[3] ADRs are recognized to be one the significant cause of hospital admissions and the incidence varied from 0.2% to 41.3%.[4] ADR monitoring in a hospital setting is an important process

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to identify the patients who are at high risk for developing ADRs and understand the nature and incidence of ADRs in a local population.[5] Thus, ADR monitoring helps in developing appropriate interventional strategies to manage, prevent and minimize the risk of developing ADRs and thereby reducing the cost of care.[6]

The association of psychotropic medications with ADRs is common and can occur even at the normal doses used in the management of acute and maintenance phases of psychiatric disorders.[7] These ADRs can impair quality of life, may lead to poor adherence to medications, cause physical morbidity, issue stigma, and in extreme cases, can be fatal.[8] Many studies have reported the incidence, nature and occurrence of ADRs to various psychotropic medications.[7,9-11] Good number of these studies has reported the incidence and nature of ADRs in patients visiting psychiatry outpatient departments (OPDs).[11-13] The study reported by Solanke *et al.* the overall incidence rate of ADRs was found to be 5.01% in psychiatry OPD of a tertiary referral center in central India.[11] Another study reported 429 (21.45%) having, at least, one ADR among 2000 patients who were screened in psychiatry OPD.[9] Psychiatric medications accounted for 45 (48.4%) of the ADRs in hospitalized psychiatric patients as reported by Thomas *et al.*[13] However, no published studies available regarding the incidence and nature of ADRs in psychiatry patients in UAE.

The awareness of the health care providers regarding ADRs of the psychotropic agents and how to manage them can foster the safe and rational use of these agents. In UAE, pharmacovigilance activity is still in its initial stages, and its importance is not very well recognized. Pharmacovigilance can play a vital role in alerting the healthcare providers from the possible ADRs and thus protecting the patients who are using psychotropic medications.[14] Therefore, the ultimate goal of our study is to enhance and strengthen the pharmacovigilance activity in UAE and foster the role of clinical pharmacist in ADR monitoring and reporting.

The study aims to (1) monitor and estimate the incidence and nature of ADRs in psychiatry OPD of a Secondary Care Hospital in Ras Al-Khaimah, UAE, (2) assess the causality of documented ADRs, (3) evaluate the nature of ADRs based on preventability, predictability and severity and (4) analyze the ADRs according to the demographic, illness characteristics and predisposing factors.

Materials and Methods

The study was conducted at psychiatry OPD of Secondary Care Hospital of Ras Al-Khaimah, UAE. This was a prospective observational study conducted from October 2013 to April 2014. The study was approved by Research and Ethics Committee. Patients of all age groups and both the gender, diagnosed with any psychiatric disorder and receiving psychotropic medications and registered in the psychiatry OPD of the study the site were monitored for ADRs and were included in the study.

Patients who were not prescribed with any psychotropic medications, suffering from malignancies, terminally ill, and drug abusers (due to the reason that they receive multiple medications, and it is more difficult to get correct conclusion regarding ADRs in these group of patients) and mentally retarded as they cannot illustrate/mention their ADRs correctly were excluded from the study.

All the patients attending psychiatry outpatient and satisfying the inclusion criteria were monitored for ADRs on four fixed days in a week by the study investigators from 09:00 a.m. to 01:00 p.m. During the study period, a total of 900 patients were expected to be monitored for ADRs. ADRs noticed by the treating psychiatrist, reported by the patient or their caretakers during regular patient consultation were documented by the clinical pharmacist. The required data was collected from the patient case files as well as from the patients themselves and their caretakers if required and was entered in the designed ADR reporting and documentation form, which includes various details such as demographic information, disease characteristics, history of ADR, medication history, and other relevant information.

The causality assessment of documented ADRs was done using Naranjo scale,[15] and WHO-The Uppsala Monitoring Centre probability scale,[16] severity was assessed using Hartwig *et al.* scale,[17] and preventability assessment using Modified Schumock and Thornton's Scale.[18]

Type of underlying disorders in patients who experienced ADRs was classified according to International Classification of Diseases Ninth Revision, Clinical Modification. Drugs and system organ class involved in ADRs were coded according to Anatomical Therapeutic Chemical Classification System and World Health Organization Adverse Reaction Terminology respectively.

Data analysis

Collected data were summated and were entered into the Microsoft-excel sheet and was analyzed using the Statistical Package for the Social Sciences (SPSS) version 18.0. (IBM, Armonk, NY, United States of America). The categorical data were presented in the form of frequency, percentage, and mean ± standard deviation Chi-square test was performed to find out the association between ADRs and sociodemographic, disease and treatment-related variables. Paired Student's *t*-test was performed to compare the significance difference in the weight of the patients who reported weight gain to psychotropic medications. $P < 0.05$ is considered as statistically significant. The results were presented in the form of text, tables, and figures.

Results

A total of 714 patients were monitored, of which 352 (49.2%) were male and 362 (50.7%) were female patients. Among the 73 patients who experienced ADR to psychotropic medications, 37 (50.7%) were males and 36 (49.3%) were females [Table 1]. The average age of the patients who experienced ADR was found to be 36.15 ± 18.7 years. The maximum numbers of ADRs were documented in the age group of 18–28 years (30.1%)

followed by 29–39 years (27.4%) [Table 2]. A total of 714 psychiatric patients visiting psychiatric OPD of the study site were reviewed during the study period, of which 73 patients experienced, at least, one ADR. The incidence of ADRs at outpatient psychiatry department was found to be (73/714 × 100) 10.2%. The average number of drugs taken by the patients who experienced, at least, one suspected ADR was found to be 2.7 ± 1.5 drugs. Majority of the patients who experienced ADR were taking one to two drugs (n = 40, 54.8%) [Table 1]. A total of 112 ADRs were observed during the study period. The overall mean number of ADRs documented in the study was found to be 1.5 ± 0.7 ADRs. Majority of the patients 46 (63.0%) experienced at least one ADR [Table 1].

Table 1: Demographic and treatment-related variables of the patients who experienced adverse drug reactions

Demographic and treatment-related variables	*n* (%) Total=73
Gender	
Male	37 (50.7)
Female	36 (49.3)
Age (in years)	
>18	07 (9.6)
18-28	22 (30.1)
29-39	20 (27.4)
40-49	11 (15.1)
50-59	04 (5.5)
>60	09 (12.3)
Nationality	
Arab	72 (98.7)
Non-Arab	01 (1.3)
Prescribed number of drugs	
1-2	40 (54.8)
3-4	24 (32.9)
>05	09 (12.3)
Number of ADRs documented/patient	
01	46 (63.0)
02	16 (21.9)
03	11 (15.1)

ADRs: Adverse drug reactions

Weight gain 18 (16.07%) was the most commonly suspected ADR followed by somnolence 8 (7.14%), constipation, dry mouth and headache 06 (5.3%) each [Tables 2 and 2a]. Weight gain has been reported in 18 cases. However, the weight (pre- and post-treatment) details of only 12 patients were available during documentation. The average weight of the patients before initiating psychotropic drugs was found to be 65.7 ± 14.1 kg, whereas after receiving suspected psychotropic therapy, it was found to be 78.9 ± 15.9 kg. This difference in the weight of the patients after receiving the suspected psychotropic treatment was found to be highly significant (P < 0.001) [Table 3]. Escitalopram 16 (14.2%) was the most commonly implicated drug in ADR followed by quetiapine 13 (11.6%) and olanzapine and fluoxetine 10 (8.9%) each [Table 4]. Atypical antipsychotics 37 (33%) followed by selective serotonin reuptake inhibitors (SSRIs) 34 (30.3%) were the most commonly involved psychotropic medications involved in ADRs [Table 5]. Depression 27 (24.10%) was the most commonly diagnosed psychiatric condition in patients who developed ADRs followed by obsessive-compulsive disorder in 18 (16.07%) cases [Table 6]. Central nervous system (CNS) 33 (29.5%) was the most commonly affected organ due to ADRs followed by gastrointestinal system 26 (23.2%) [Table 7].

Majority of the suspected ADRs were possible in nature 60 (53%) followed by probable type 38 (34%) [Table 8]. Majority of the

Table 2: Spectrum of different adverse drug reactions and drug (s) implicated

Type of ADRs	*n* (%) (*n*=112)	Drug (s) implicated
Weight gain	18 (16.07)	Quetiapine (*n*=6), olanzapine (*n*=3), escitalopram (*n*=2), mirtazapine (*n*=2), clomipramine (*n*=2), paroxetine (*n*=1), risperidone (*n*=1), aripiprazole (*n*=1)
Somnolence	08 (7.14)	Quetiapine (*n*=2), olanzapine (*n*=2), valproic acid (*n*=1), clozapine (*n*=1), mirtazapine (*n*=1), fluoxetine (*n*=1)
Constipation	06 (5.35)	Venlafaxine (*n*=2), clomipramine (*n*=2) valproic acid (*n*=1), risperidone (*n*=1)
Dry mouth	06 (5.35)	Quetiapine (*n*=4), valproic acid (*n*=1), aripiprazole (*n*=1)
Headache	06 (5.35)	Venlafaxine, clozapine, gabapentin, paroxetine, methylphenidate, carbamazepine (1 each)
Decreased appetite	05 (4.46)	Methylphenidate (*n*=2), fluoxetine (*n*=1), risperidone (*n*=1), atomoxetine (*n*=1)
Insomnia	05 (4.46)	Fluoxetine, escitalopram,venlafaxine, aripiprazole, olanzapine (1each)
Irritability	05 (4.46)	Escitalopram (*n*=2), paroxetine (*n*=1), fluoxetine (*n*=1), aripiprazole (*n*=1)
Dizziness	04 (3.57)	Fluoxetine (*n*=2), paroxetine (*n*=1), carbamazepine (*n*=1)
Nausea	03 (2.67)	Fluoxetine , escitalopram, carbamazepine (1 each)
Abdominal pain	03 (2.67)	Escitalopram (*n*=2), methylphenidate (*n*=1)
Tremor	03 (2.67)	Venlafaxine, paroxetine, haloperidol (1 each)
Impaired memory	03 (2.67)	Carbamazepine (*n*=3)
Restlessness	03 (2.67)	Aripiprazole, escitalopram, olanzapine (1 each)
Postural hypotension	03 (2.67)	Alprazolam , clomipramine, escitalopram (1 each)
Sexual dysfunction	02 (1.78)	Paroxetine, quetiapine (1 each)
Increased appetite	02 (1.78)	Paroxetine, escitalopram (1 each)
Anxiety	02 (1.78)	Fluoxetine (*n*=2)
Acne	02 (1.78)	Carbamazepine, clomipramine (1 each)
Diabetes mellitus	02 (1.78)	Olanzapine (*n*=2)

ADRs: Adverse drug reactions

Table 2a: Spectrum of other adverse drug reactions and drug (s) implicated

Type of ADRs	*n* (%) (*n*=112)	Drug (s) implicated
Hypersexual behavior	01 (0.89)	Escitalopram
Loss of interest in sex	01 (0.89)	Escitalopram
Amenorrhea	01 (0.89)	Valproic acid
Cystitis	01 (0.89)	Valproic acid
Dystonia	01 (0.89)	Olanzapine
Tardive dyskinesia	01 (0.89)	Clonazepam
Akathisia	01 (0.89)	Risperidone
Hypertension	01 (0.89)	Atomoxetine
Tachycardia	01 (0.89)	Atomoxetine
Bradycardia	01 (0.89)	Escitalopram
Palpitation	01 (0.89)	Paroxetine
Tinnitus	01 (0.89)	Escitalopram
Taste perversion	01 (0.89)	Valproic acid
Agitation	01 (0.89)	Fluoxetine
Numbness	01 (0.89)	Methylphenidate
Skin lesions	01 (0.89)	Carbamazepine
Abnormal thinking	01 (0.89)	Risperidone
Automatism	01 (0.89)	Risperidone
Odd behavior	01 (0.89)	Valproic acid
Hallucination	01 (0.89)	Quetiapine
Neck/shoulder pain	01 (0.89)	Escitalopram

ADRs: Adverse drug reactions

Table 3: Body weight profile of the patients who reported weight gain

Weight of the patients	*n*	Mean±SD (in kg)	df	Significant (two-tailed)
Pretreatment	12	65.7±14.1	11	$P<0.001$**
Posttreatment	12	78.9±15.9		

**$P<0.001$ is considered statistically highly significant by *t*-test.
SD:Standard deviation

Table 4: Psychotropic drugs associated with adverse drug reactions

Name of the drug	*n* (%) (*n*=112)
Escitalopram	16 (14.28)
Quetiapine	14 (12.5)
Olanzapine, fluoxetine	10 (8.9) each
Carbamazepine, paroxetine	08 (7.1) each
Valproic acid	07 (6.2)
Risperidone, clomipramine	06 (5.3) each
Venlafaxine, aripiprazole, methylphenidate	05 (4.4) each
Mirtazapine, atomoxetine	03 (2.6) each
Clozapine	02 (1.7)
Haloperidol, alprazolam, clonazepam, gabapentin	01 (0.89) each

suspected ADRs were possible 51 (45.5%) in nature followed by probable type 39 (34.9%) [Table 8]. Severity assessment of suspected ADRs was done using Hartwig's severity assessment. Majority of the suspected ADRs were mild in nature 98 (87%) followed by moderate type 14 (13%) [Table 8]. Preventability assessment of suspected ADRs was done using Modified Schumock and Thornton scale. Majority of the suspected

Table 5: Different class of psychotropic drugs involved in adverse drug reactions

Class of psychotropic drugs	*n* (% of ADR) (*n*=112)
Antipsychotics	
Atypical antipsychotics	37 (33.0)
Typical antipsychotics	01 (0.89)
Antidepressants	
Tricyclic antidepressants	06 (5.3)
Tetracyclic antidepressants	03 (2.6)
Selective serotonin reuptake inhibitors	34 (30.3)
Selective norepinephrine reuptake inhibitors	05 (4.4)
Antiepileptics	16 (14.3)
Central nervous system stimulants	05 (4.4)
Norepinephrine reuptake inhibitors	03 (2.6)
Anxiolytics	02 (1.7)

ADR: Adverse drug reaction

Table 6: Type of underlying disorders in patients who experienced adverse drug reactions

Psychiatric disorders	*n* (% of ADR) (*n*=112)
Depression	27 (24.10)
Obsessive compulsive disorder	18 (16.07)
Epilepsy	15 (13.39)
Schizophrenia	13 (11.60)
Bipolar-mania	08 (7.14)
Generalized anxiety disorder	06 (5.35)
Attention deficit hyperactivity disorder	05 (4.46)
Depression and anxiety	05 (4.46)
Dementia	05 (4.46)
Autism spectrum disorder	04 (3.57)
Panic disorder	03 (2.67)
Stuttering	02 (1.78)
Somatization disorder	01 (0.89)

ADR: Adverse drug reaction

Table 7: Organ systems associated with adverse drug reactions

System organ class (WHO-ART SOC code)	*n* (%) (*n*=112)
Central and peripheral nervous system disorders (0410)	33 (29.5)
Gastro-intestinal system disorders (0600)	26 (23.2)
Metabolic and nutritional disorders (0800)	20 (17.9)
Psychiatric disorders (0500)	15 (13.4)
Cardiovascular disorder (1010)	04 (3.6)
Heart rate and rhythm disorder (1030)	03 (2.7)
Skin and appendages disorder (0100)	03 (2.7)
Reproductive system disorders male (1410)	03 (2.7)
Reproductive system disorders female (1420)	02 (1.7)
Hearing and vestibular Disorders (0432)	01 (0.9)
Musculoskeletal disorder (0200)	01 (0.9)
Urinary system disorders (1300)	01 (0.9)

SOC: System-organ classification, WHO-ART: World Health Organization-Adverse Reaction Terminology

ADRs 92 (82.1%) were of not preventable type followed by probably preventable 17 (15.17%) [Table 8].

In majority of the cases the drug was withdrawn 46 (41.1%) to manage ADRs followed no change in the prescribed psychotropic medications 37 (33.0%) [Table 9]. In majority of the suspected, ADRs were treated symptomatically 45 (40.2%) followed by no treatment in 36 (32.1%) cases [Table 9]. Majority of the suspected ADRs 52 (46.4%) were recovered followed by continuation of suspected ADR in 38 (34.0%) cases [Table 9]. For majority of the cases, no dechallenging was done 60 (53.6%) followed by definite improvement of ADRs in 44 (39.2%) cases after dechallenging. While no rechallenge was done for majority of 104 (92.9%) suspected ADRs [Table 9].

A Pearson Chi-square test was conducted to examine whether there was a relationship between demographic/treatment related variables with the number of suspected ADRs. The results showed that there was no significant relationship between gender (χ^2 = 0.89, df = 2, P = 0.06), age (χ^2 = 10.87, df = 10, P = 0.36), nationality status (χ^2 = 0.59, df = 4, P = 0.74) and prescribed number of medications (χ^2 = 3.24, df = 4, P = 0.51).

Discussion

The overall incidence rate of ADRs in our study was found to be 10.2%. However, many international studies have reported an overall incidence rate of 5.01–21.45% in psychiatry OPDs.[7-11] In contrast to our findings, a study conducted by Shah and Mehta reported an incidence rate of 0.67% in psychiatry outpatients.[19]

Weight gain was the most commonly implicated ADR in the present study. Many ADR related studies conducted in this area have reported weight gain as one of the most commonly observed ADR in patients taking a certain class of psychotropic medications.[20-25] In our study, majority of the weight gain were documented for atypical antipsychotics, followed by SSRIs, selective norepinephrine reuptake inhibitors, and tricyclic antidepressants. As reported in the literature the possible mechanisms for weight gain include $5HT_{2c}$ antagonism, H_1 antagonism, hyperprolactinemia and increased serum leptin.[26] Furthermore, improvement of the underlying mental disorder like depression could lead to increase appetite and weight gain. It is suggested that switching the medication or psychotherapy, education, and healthy lifestyle will be beneficial in treating the drug-induced weight gain.[27]

Somnolence/sedation/oversleep was the second most common ADR documented in our study. However, few studies have reported tremor as the most commonly noted ADR followed by weight gain.[7,9,28] This difference in the findings could be due to the difference in the prescribing pattern of psychotropic medications and may be influenced by the number and type of psychiatric patients visiting the OPD as reported in other ADR monitoring studies.[29]

CNS adverse effects such as somnolence/sedation are common with psychotropic medications because these drugs act on CNS. It is documented that sedation persists for first few months, but usually wears off.[30] It is noteworthy to mention that apart from the well-known ADRs, we noticed two additional ADRs, where occurrence or incidences of which has not been well documented or reported in any standard literatures. One such ADR is hypersexual behavior and the other one is total loss of interest in sex reported by a female

Table 8: Causality assessment of suspected adverse drug reactions

Assessment	*n* (% of ADR) (*n*=112)
Naranjo causality assessment	
Definite	10 (09)
Probable	38 (34)
Possible	60 (53.5)
Doubtful	04 (3.5)
WHO probability assessment	
Certain	16 (14.3)
Probable	39 (34.9)
Possible	51 (45.5)
Unclassifiable	01 (0.9)
Unlikely	02 (1.8)
Conditional	03 (2.7)
Hartwig's severity assessment	
Mild	98 (87)
Moderate	14 (13)
Preventability assessment	
Not preventable	92 (82.1)
Probably preventable	17 (15.2)
Definitely preventable	03 (2.7)

ADR: Adverse drug reaction, WHO: World Health Organization

Table 9: Outcome of suspected adverse drug reactions

Outcome	*n* (% of ADR) (*n*=112)
Management of suspected ADRs	
Drug withdrawal	46 (41.1)
Does altered	29 (25.9)
No change	37 (33.0)
Treatment of suspected ADRs	
Specific	31 (27.7)
Symptomatic	45 (40.2)
Nil	36 (32.1)
Outcome of suspected ADRs	
Fatal	00 (00)
Recovery	52 (46.4)
Continuing	38 (34.0)
Partial improvement	16 (14.2)
Unknown	06 (05.4)
Dechallenge of suspected ADRs	
Unknown	03 (2.7)
No improvement	05 (4.5)
Definite improvement	44 (39.2)
No dechallenge	60 (53.6)
Rechallenge of suspected ADRs	
No occurrence	00 (00)
Recurrence of symptom	08 (7.1)
No rechallenge	104 (92.9)

ADRs: Adverse drug reactions

and male patient respectively. Interestingly, both these ADRs were reported for escitalopram. It is well documented in the literature that escitalopram causes decreased libido (3–7%) and impotence (2–3%), but hypersexual behavior and total loss of interest in sex are not well documented.[31] However, further examination on this issue could be helpful in determining the exact reason or to confirm whether such behavior is psychiatry disorder related. Decrease libido and impotence are both common in depression and would respond to escitalopram which could explain the hypersexuality reported or due to drug. The male patient, who reported having loss of interest in sex, denied having impotence.

Another two rare ADRs noticed in the study were restlessness to olanzapine, which is documented in the adolescent population. However, in this study, it was reported by a geriatric patient could be akathisia, which is a common side effect with antipsychotics and in another incidence automatism, which is most commonly documented in children, but it was reported by an adult schizophrenic patient.

One more important observation documented in the current study was out of 112 suspected ADRs, the incidence of 16 ADRs were <1%. Examples of such ADRs include tardive dyskinesia, which is a remote side effect and shown only after years associated with clozapine. It was observed that limited numbers of patients were on clozapine.[32] In addition, we noticed two unusual ADRs such as dystonia implicated with olanzapine and restlessness and irritability due to escitalopram usage.

Majority of the suspected ADRs were possible in nature. While good number of ADRs were mild in nature and were of not preventable type. A study conducted by Prajapati *et al.* reported higher number of ADRs, which were moderate in nature.[9] However, few other studies have reported higher number of ADRs, which are mild in nature.[10] In contrast, several studies have reported serious or fatal ADRs to a different class of psychotropic medications such as antidepressants and atypical antipsychotic medications.[33-35] A recent study has reported that even ADR, which is "not severe" in nature can have a significant impact on patients with psychiatry illness.[36] Hence, managing and preventing ADR in psychiatric illness patients is vital.

Majority of the suspected ADRs were not of preventable type. In contrast to our findings, a study conducted by Nithya *et al.* reported that all the ADRs to psychotropic drugs were not preventable type.[21] In another study conducted by Lahon *et al.* good number of the ADRs were probably preventable.[22] While another study assessing the preventability of ADR reported only 19 preventable ADRs among 94 suspected ADRs.[13] Another study highlighted the role of the pharmacist in preventing ADRs and 87 pharmacist interventions were recognized as preventable ADRs.[37]

As reported in the literature occurrence of ADR may lead to nonadherence to medications.[8] In the present study, we noticed five patients out of 73, who have stopped their medication on their own at home after the development of ADR. This observation supports the fact that ADR might lead to nonadherence or discontinuation of therapy.

Age, gender, number of drugs received/polypharmacy and race are known to be the predisposing factors of ADRs.[38] In contrast to our findings, a study conducted by Kasper *et al.* identified age and male sex as the indicators of tardive dyskinesia in schizophrenia patients.[39] This study was limited only to ADR such as tardive dyskinesia.

The main limitation of the present study was short duration of the study period. Study duration of more than 1 year could be more beneficial in identifying the wide spectrum of ADRs to wide variety of medications. In addition, majority of the ADRs identified during study duration were mild in nature. No fatal/serious ADRs were reported or documented in the outpatient clinic, as the patients who develop serious ADRs will be admitted to emergency room directly followed by inpatient department. No rechallenging was done or was possible for majority of the ADRs. Our study did not document and categorize the type and number of ADRs based on the duration of use of medication and new versus old patients. It was difficult to obtain required information from few patients who were non-Arabic and non-English (not fluent) speakers. In the present study, the outpatient type was mainly limited to nationals, students below 18 years of age and to those patients who have a health care facility. This resulted in limiting the number of patients visiting the OPD of the study site.

Conclusion

The present study offers a representative profile of the ADRs which can be expected in the psychiatry outpatients department in UAE. The study revealed a moderate incidence of ADRs in patients attending the psychiatry OPD. Majority of the ADRs reported during the study were mild in nature and not preventable type. Good number of the ADRs recovered upon withdrawal of the drug or after dose is altered. The study fosters the role of clinical pharmacist in the monitoring and reporting of ADRs. Regular intensive monitoring of ADRs in psychiatry OPD settings by clinical pharmacist might help in early detection of ADRs and reduce the risk caused by ADRs and thereby it may improve the quality of care, reduction in the treatment cost and enhancement of medication adherence pattern among patients.

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There are no conflicts of interest.

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