The relationship between self-reported antipsychotics side effects and depression in Saudi Arabia

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ABSTRACT

Background: The utilization rate of antipsychotics to treat different mental disorders is rising. However, little is known about their side effects' impact on depression levels. Therefore, the objective of this study was to examine the association between antipsychotic side effects and depression among psychiatric patients treated with antipsychotics.
Methods: This is a prospective, single-center, interview-based, cross-sectional study that examined the association between antipsychotic side effects and depression among adult patients (e.g., ≥ 18 yrs.) with psychiatric illnesses (e.g., depression, schizophrenia, bipolar disorder) visiting outpatient clinics in a university-affiliated tertiary care center. Antipsychotic side effects were assessed using the Arabic version of the Glasgow Antipsychotic Side-effect Scale (GASS), while depression was assessed using the Arabic version of the 9-item Patient Health Questionnaire (PHQ-9). Univariate and multiple linear regressions were conducted to examine the association between the PHQ-9 and GASS scores.
Results: One hundred patients met the inclusion criteria and consented to participate. Most of the patients were females (72 %) with a mean age of 38 years. Schizophrenia (37 %) and bipolar disorder (54 %) were the most common mental disorders among the recruited patients. The majority of patients were treated with atypical (e.g., second-generation) antipsychotics (88 %) for at least six months (74 %). Controlling for age, gender, annual family income, education, employment status, marital status, number of comorbidities, duration of treatment with antipsychotics, the type of antipsychotic, and psychiatric illness, higher GASS scores, which indicate more severe antipsychotic side effects, predicted higher PHQ-9 score (e.g., higher levels of depression) ($\beta = 0.419$, 95 % CI=[0.307–0.532], *p*-value < 0.0001).
Conclusion: Early identification and management of antipsychotic side effects among psychiatric patients should enhance patient adherence and improve treatment outcomes. Future studies should verify the findings of this study using more robust study designs.

1. Introduction

The prevalence of mental illness is increasing, and it is estimated that 1 in 8 people live with a mental health condition in the world. However, 71 % of people with psychosis do not receive mental health services, and, only 2 % of the healthcare budgets are allocated to mental health, according to the World Mental Health Report (WHO, 2022). Anxiety and depression disorders represent nearly 60 % of the reported mental illnesses, followed by idiopathic developmental disorders (11.1 %), attention deficit hyperactivity disorder (8.8 %), bipolar disorder (4.1 %), conduct disorders (4.1 %), autism spectrum disorders (2.9 %), schizophrenia (2.5 %), and eating disorders (1.4 %) (WHO, 2022). In Saudi

Arabia, there are no accurate statistics on the prevalence and incidence rates of mental illness (Almutairi 2015). However, based on a recently published systematic review and *meta*-analysis that investigated the prevalence of depression among Saudi adults, the pooled prevalence rate was 37.35 % (Nour et al., 2023).

The management of mental illness includes different approaches, such as psychotherapies, pharmacotherapies, and electroconvulsive therapy (Leichsenring et al., 2022). However, pharmacotherapies, such as antidepressants and antipsychotics, are the mainstay in mental disorders treatment (Locke et al., 2015, Gautam et al., 2017, Keepers et al., 2020, Kate and Zachary 2022). Antipsychotics are commonly used in the management of several mental disorders, such as treatment-resistant

depression, anxiety, schizophrenia, and bipolar disorders (Keepers et al., 2020). Despite being widely used in the management of different mental disorders, their side effects might be intolerable to many patients, leading to poor medication adherence and, eventually, poor clinical outcomes (Muench and Hamer 2010, Stroup and Gray 2018, Bahta et al., 2021). These side effects can be minor (e.g., sedation, dry mouth), moderate (e.g., constipation, sexual dysfunction, akathisia, weight gain), and severe (e.g., myocarditis, agranulocytosis) (Stroup and Gray 2018).

Higher rates of side effects were observed among patients with treatment-resistant depression (TRD) with higher levels of depression and anxiety (McIntyre et al., 2023), those with childhood trauma, low self-esteem, and suicidal ideations, according to a cross-sectional multicenter study that utilized retrospective data from the French network of Expert Centers for TRD in France (Levy et al., 2021). However, no study has so far investigated the relationship between the rates of antipsychotics' side effects and depression among mental health disorders patients on first- or second-generation antipsychotics. Therefore, this study aimed to examine the association between self-reported antipsychotic side effects and depression among mental health disorders patients in Saudi Arabia.

2. Methods

2.1. Study design and population

This cross-sectional study took place at a university-affiliated tertiary care center in Riyadh, Saudi Arabia. The participants were patients with mental disorders (such as TRD, bipolar disorder, schizophrenia) who were being treated with antipsychotics and visiting outpatient psychiatry clinics. The patients were identified from a list of those with scheduled follow-up visits between June 2016 and August 2017. Treatment-resistant depression (TRD) was defined as the failure to respond to at least two different antidepressant medications, despite adequate duration (e.g., ≥ 6 weeks) and adherence to therapy. This definition is consistent with the criteria established by the United States Food and Drug Administration (USFDA) and the European Medicines Agency (EMA) (McIntyre et al., 2023). Information about each patient's medical history (including mental disorders, other health conditions such as diabetes and hypertension, prescription medications including psychotropic medications, and the date of initiation of antipsychotics) as well as general sociodemographic characteristics (e.g., age, gender, nationality) was retrieved from the electronic medical records. Excluded from the study were patients not treated with antipsychotics either first- or second-generation antipsychotics, those who were treated with antipsychotics in the past but were not taking them at the time of the study, patients with dementia, hospitalized patients, pregnant women, and non-adults (i.e., <18 years of age). Two pharmacy interns were involved in the data collection and patient interviews in a private room at the outpatient psychiatry clinics immediately following the patient visits. Patients were approached while waiting time at the clinics by the two pharmacy interns, who introduced themselves and explained the purpose of the study to the patients. To minimize the interviewer bias, the interns followed an interview protocol and underwent training using role-play techniques to ensure that they adhere to the protocol (Bergelson et al., 2022). Patients who agreed to participate signed a consent form and were then invited to a private room after their psychiatric appointments. The interview, which lasted between 15 and 20 min, covered topics including the side effects of the antipsychotics, depression, employment status, marital status, monthly income, and educational level.

2.2. Study tools

Antipsychotics' side effects were assessed using the Arabic version of the Glasgow Antipsychotics Side effects Scale (GASS) (AlRuthia et al.,

2018). GASS consists of 20 questions with five possible choices ("never = 0", "once = 1", "a few times = 2", "every day = 3", and distressing) and two questions with two possible choices ("Yes = 3" or "No = 0") in which one of these two questions is specific only to females resulting a maximum score of 63 indicating the most severe side effects and a lowest possible score of 0 indicating no side effects at all. The scale covers a wide range of antipsychotic side effects (prolactinemic, anticholinergic, gastrointestinal, nervous system, cardiovascular, and extrapyramidal). It is commonly used to screen psychiatric patients about any potential side effects that might be caused by antipsychotics in different psychiatry clinics (Waddell and Taylor 2008). On another hand, depression was assessed by the Arabic version of the 9-item Patient Health Questionnaire (PHQ-9), which consists of 9 questions inquiring about a group of symptoms associated with depression over the past two weeks with four possible choices ("0 = Not at all", "1 = Several Days", "2 = More Than Half the Days", "3 = Nearly Every Day") (AlHadi et al., 2017). The PHQ-9 is designed for screening, diagnosing, monitoring, and measuring the severity of depression and has been validated among different psychiatric patient populations with higher scores indicating more severe levels of depression (Kroenke et al., 2001, Arroll et al., 2010, Inoue et al., 2012, Manea et al., 2015, Beard et al., 2016, Chen et al., 2023).

2.3. Statistical analysis

The minimum sample size needed for this study was estimated to be 55 patients for multiple linear regression and up to 11 predictors using a medium effect size (Cohen's $f^2 = 0.15$), $\beta = 0.2$, and 80 % power. Descriptive statistics, such as mean, standard deviation, frequencies, and percentages, were used to present the baseline characteristics of the patients. In order to examine the relationship between depression using the PHQ-9 score and antipsychotic side effects using the GASS score, univariate and multiple linear regressions were conducted. The multiple linear regression adjusted for multiple confounders, including age, gender, education, employment status, number of comorbidities, mental illness, duration of treatment with antipsychotics, marital status, and type of antipsychotics (typical or atypical). All statistical analyses were conducted using SAS® version 9.4 (SAS® Institute, Cary, NC, United States).

2.4. Ethical considerations

All recruited patients had consented to participate in the study and signed a written consent form explaining the purpose of the study and their right to withdraw from the study at any time without penalty. Collected data were anonymized, encrypted, and stored in a safe place. No personal identifiers, such as addresses, national ID numbers, or electronic medical record numbers, were collected. The study adhered to the ethical principles of the Helsinki Declaration and was approved by the institutional review board of the College of Medicine at King Saud University, Riyadh, Saudi Arabia (Research Project No. E-16-1943) (Association, 2014).

3. Results

Out of 179 patients who were invited to participate, 100 patients accepted the invitation and consented to participate. Most participants were females (72 %), and their mean age was 38 years. About two-thirds of the participants had a high-school diploma or less (61 %), 72 % were unemployed, 59 % were unmarried (divorced or single), and 50 % had an annual family income of SAR 72,000 or less. More than 50 % of participants were taking only one prescription medication, 54 % had bipolar disorder, 37 % had schizophrenia, 9 % had TRD, and 88 % were on second-generation antipsychotics (atypical antipsychotics). Based on the PHQ-9 score, the percentage of patients with moderate to severe depression was 52 %. On the other hand, the percentage of patients with moderate to severe antipsychotic side effects was 71 %. The percentage

of patients who had other chronic health conditions, besides psychiatric illnesses, such as diabetes, hypertension, peptic ulcer, chronic obstructive pulmonary disease, and chronic kidney disease was 40 %, as shown in Table 1.

With every single unit increase in the score of GASS, there is a 0.409-unit increase in the PHQ-9 score ($\beta = 0.409$, 95 % CI=[0.299–0.518], p-value < 0.0001) based on the findings of the univariate linear regression analysis as shown in Fig. 1. This positive relationship between PHQ-9 and GASS scores was confirmed in the multiple linear regression analysis ($\beta = 0.419$, 95 % CI=[0.307–0.532], p-value < 0.0001) controlling for age, gender, educational level, employment status, marital status, annual family income, psychiatric diagnosis, number of comorbidities, duration of treatment with antipsychotics, and type of antipsychotic (typical *versus* atypical). Moreover, patients' annual family income was associated with higher PHQ-9 scores ($\beta = 1.108$, 95 % CI= [0.083–2.133], p-value $= 0.035$), as shown in Table 2.

4. Discussion

The management of psychiatric illnesses is multifactorial and entails the collaboration between different healthcare providers, such as psychiatrists, psychologists, pharmacists, social workers, and the families of affected individuals (Reist et al., 2022). Therefore, treatment optimization through choosing the right prescription drugs for different psychiatric illnesses, improving medication adherence, and identifying psychotropic drugs' side effects that could negatively impact patient adherence to treatment are essential to ensure favorable clinical outcomes (Stroup and Gray 2018, Leichsenring et al., 2022). Antipsychotics are widely utilized to manage different psychiatric illnesses, such as treatment-resistant depression, bipolar disorder, and schizophrenia, and are associated with a myriad of side effects. In this study, the severity of antipsychotics' side effects, which was assessed using the Arabic version of GASS, was correlated with higher depression levels. This positive relationship between the self-reported antipsychotic side effects and depression remained significant even after controlling for age, gender, income, education, psychiatric condition, type of antipsychotic, number of comorbidities and prescription drugs, and duration of treatment with antipsychotics.

Even though antipsychotics are commonly used to manage TRD due to their adjunctive antidepressive effects (Roberts et al., 2016), there is limited evidence regarding their efficacy in bringing about a clinically meaningful improvement mainly due to their adverse events profile (e. g., weight gain, metabolic dysfunction, and extrapyramidal symptoms) (Jha and Mathew 2023). Additionally, their impact on health-related quality of life (HRQoL) is not unequivocally positive, as one of the research papers that investigated their impact when used as an adjunctive therapy alongside antidepressants among TRD patients using nationally representative data from the United States found (Al-Ruthia et al., 2015). This uncertainty and controversial findings on the impact of antipsychotics on depression could arguably be due to their side effects profile (Al-Ruthia et al., 2015, Jha and Mathew 2023). Therefore, examining the relationship between antipsychotic side effects and levels of depression is crucial to optimize therapy and improve clinical outcomes among patients with different mental health conditions (e.g., schizophrenia, bipolar disorder, depression). The positive association between the severity of antipsychotic side effects and depression, as demonstrated in this study, underscores the need for regular screening for antipsychotic side effects and the adoption of different measures (e. g., dose adjustment, switching to another antipsychotic with better side effects profile, switching to a long-acting formulation of antipsychotics) to mitigate these adverse effects and enhance patient adherence to treatment leading to improved overall health outcomes (Poloni et al., 2019).

Other patient characteristics, such as education, female gender, employment status, number of comorbidities, duration of treatment, marital status, psychiatric illness, and type of antipsychotic (e.g., first or

Table 1
Patients baseline characteristics (n = 100).

| Characteristic	Frequency (%)
Gender	
Male	28 (28 %)
Female	72 (72 %)
Age, mean ± SD	38.43 ± 10.42
Education	
Intermediate school or less	36 (36 %)
High school diploma	25 (25 %)
University degree	39 (39 %)
Marital status	
Married	41 (41 %)
Single	44 (44 %)
Divorced	15 (15 %)
Diagnosis	
Treatment-resistant depression	9 (9 %)
Schizophrenia	37 (37 %)
Bipolar disorder	54 (54 %)
Duration of treatment with antipsychotics	
<2 month	9 (9 %)
2-3 months	6 (6 %)
4-5 months	11 (11 %)
6-7 months	4 (4 %)
8-9 months	11 (11 %)
>9 months	59 (59 %)
Number of prescription medications, mean ± SD	
1	58 (58 %)
2-4	31 (31 %)
5-7	9 (9 %)
≥8	2 (2 %)
Type of antipsychotics	
Typical (e.g., haloperidol, chlorpromazine)	12 (12 %)
Atypical (e.g., clozapine, aripiprazole, paliperidone)	88 (88 %)
Other medical conditions	
Diabetes	22 (22 %)
Hypertension	10 (10 %)
Peptic ulcer	1 (1 %)
Chronic obstructive pulmonary disease	5 (5 %)
Chronic kidney disease	2 (2 %)
Employment status	
Employed	28 (28 %)
Unemployed	72 (72 %)
Annual family income in Saudi Riyals (SAR)	
≤SAR 36,000	30 (30 %)
SAR 36,001 – SAR 72,000	20 (20 %)
SAR 72,001 – SAR 120,000	19 (19 %)
SAR 120,001 – SAR 180,000	10 (10 %)
SAR 180,001 – SAR 240,000	7 (7 %)
SAR 240,001 – SAR 300,000	14 (14 %)
Depression severity based on PHQ-9 scores	
None (0–4)	25 (25 %)
Mild (5–9)	23 (23 %)
Moderate (10–14)	22 (22 %)
Moderately severe (15–19)	20 (20 %)
Severe (20–27)	10 (10 %)
Side effects severity based on GASS score	
Absent/mild side effects (0–12)	29 (29 %)
Moderate side effects (13–26)	46 (46 %)
Severe side effects (>26)	25 (25 %)
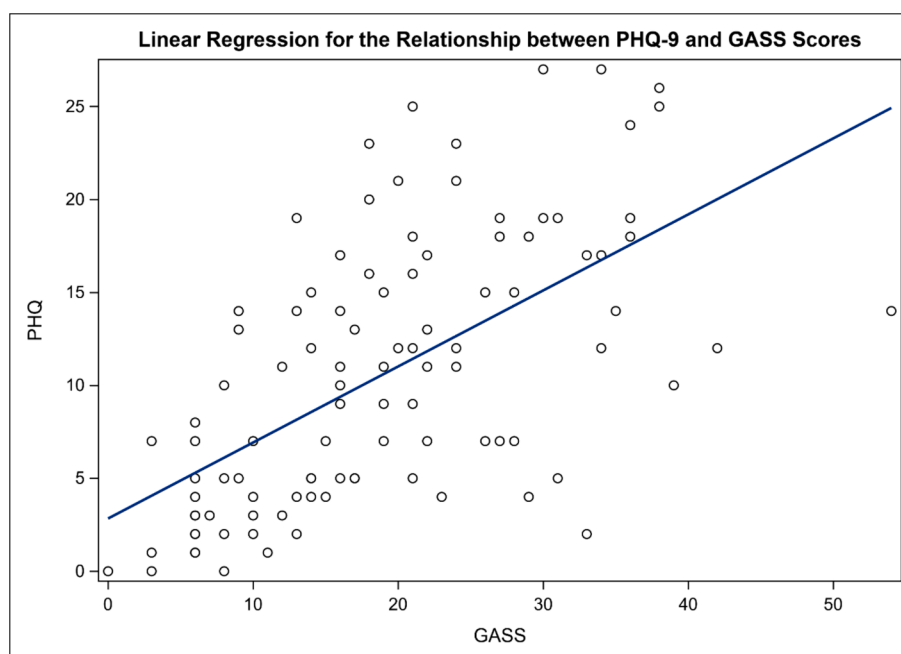
Fig. 1. Univariate linear regression on the relationship between the 9-item Patient Health Questionnaire (PHQ-9) and Glasgow Antipsychotic Side-effect Scale (GASS).

Table 2
Multiple linear regression on the relationship between PHQ-9 and GASS scores.

Variable	β-regression coefficient	p-value	95 % Confidence limits	
			Lower	Upper
GASS score	0.419	0<.0001	0.307	0.532
Age	−0.02	0.745	−0.183	0.132
Gender (Male vs. Female)	−0.831	0.571	−3.738	2.075
Income	1.108	0.035	0.083	2.133
Educational level	0.319	0.435	−0.489	1.128
Employment status	−1.922	0.233	−5.105	1.261
Number of comorbidities	−1.037	0.246	−2.805	0.731
Duration of treatment	0.391	0.258	−0.291	1.072
Marital status	−1.042	0.268	−2.901	0.815
Psychiatric diagnosis	0.342	0.063	−0.019	0.703
Typical *versus* atypical antipsychotics	1.567	0.424	−2.313	5.448

second generation) were not significantly associated with depression despite other numerous studies that found a relationship between these medical and sociodemographic characteristics and level of depression (Freeman et al., 2016, Schlax et al., 2019). Although higher income was associated with lower odds of depression in most of the published research studies (Zare et al., 2022), this relationship is nonlinear, and higher income can be associated with higher levels of depression, as one of the studies has found (Li et al., 2022). In this study, higher annual family income was associated with higher levels of depression despite controlling for a myriad of factors, such as age, gender, number of comorbidities, education, employment status, and others.

Although this is the first study, to the best of our knowledge, to examine the association between self-reported antipsychotic side effects and depression, several limitations must be acknowledged, first, this is a single-center cross-sectional study with a small sample size and convenience sampling, limiting the findings' generalizability. Moreover, no causality can be established between antipsychotic side effects and depression since this is an observational study. Furthermore, the severity of depressive symptoms was assessed using the Arabic version of the PHQ-9, which is a valid tool but has some limitations with regard to its specificity in measuring depressive symptoms among certain

psychiatric patient populations, such as those with schizophrenia (Inoue et al., 2012). Finally, the side effects of antipsychotics were examined using a valid self-report scale and were not verified by clinicians.

5. Conclusion

The positive association between depression and antipsychotic side effects underscores the importance of screening for medication side effects and timely management of these adverse effects to enhance medication adherence and improve clinical outcomes. Future studies should examine this association using larger sample sizes, diverse patient populations, and more robust study designs.

CRediT authorship contribution statement

Yazed AlRuthia: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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