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Adherence to the monitoring of metabolic syndrome in patients receiving antipsychotics in outpatient clinics in Saudi Arabia

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Abstract:

BACKGROUND: Monitoring protocols have been developed because patients taking atypical antipsychotics are more prone to developing metabolic syndrome, which leads to possible increased mortality and morbidity. The aim of this study was to assess the degree of adherence to the recommendations of metabolic syndrome monitoring.

MATERIALS AND METHODS: This study was conducted in two large psychiatric facilities in the Eastern Province of Saudi Arabia. A retrospective analysis of the medical records of 350 patients taking antipsychotic medications was done, and an assessment was made of the frequency of metabolic monitoring at each of the intervals as suggested by the American Diabetes Association. Data was analyzed using SPSS; descriptive statistics. were computed and Chi-square test was used to determine statistical significance for association between categorical variable.

RESULTS: The mean age of the patients was 34.9 ± 18 years; 64.6% were males. Olanzapine was the most prescribed medication (43.7%, *n* = 153), followed by quetiapine (17.4%, *n* = 61). Only one-third of the patients (29.6%) completed all the baseline parameters. Documentation of baseline parameters was low for glucose level (38.9%), lipid panel (17.3%), weight (25.2%), and waist circumference (1.4%). Adherence to yearly monitoring was much lower than at baseline (mean percentage: 29.6% vs. 1.7%). Furthermore, 45% of the patients were classified as obese and 10% had metabolic comorbidity.

CONCLUSION: Individuals with mental illness who were taking antipsychotics did not undergo proper metabolic screening during antipsychotic treatment. Barriers to adherence to the monitoring guidelines should be examined and addressed. Giving assistance to practitioners to recall the required laboratory tests and vitals at certain intervals could help improve metabolic monitoring practices.

Keywords:

Antipsychotics, drug monitoring, guideline adherence, metabolic syndrome, Saudi Arabia

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Introduction

Metabolic comorbidities such as diabetes and dyslipidemia, disability, high health-care costs, and premature mortality are factors linked to severe mental illness, making it a serious public health concern.[1] Atypical antipsychotics are often the first-line treatment for schizophrenia, schizoaffective disorder, bipolar disorder, and other mental disorders. Second-generation antipsychotics (SGAs) are effective treatments for a variety of mental illnesses such as schizophrenia and bipolar disorder. Despite treatment success, increasing attention has been paid to metabolic abnormalities and their

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associated side effects.[2] Although SGAs have a reduced risk of extrapyramidal symptoms compared to first-generation antipsychotics, they have a higher risk of metabolic side effects.[3] Increased mortality and morbidity from cardiovascular and endocrine system dysfunctions are attributable to the cluster of risk factors known as metabolic syndrome.[4] Cardiovascular disease, particularly coronary heart and cerebrovascular diseases, is the primary cause of death in individuals with serious mental illnesses such as schizophrenia.[5,6] Metabolic syndrome refers to the concurrent presence of multiple known cardiovascular risk factors, including obesity, insulin resistance, dyslipidemia, and hypertension (HTN).[7] Metabolic syndrome can be induced by the long-term use of antipsychotics.[8] Many researchers and clinicians use the National Cholesterol Education Program Adult Treatment Panel III guidelines to diagnose metabolic syndrome. A patient is considered to have metabolic syndrome if they have three or more of the following five symptoms or findings: waist circumference (WC) >40″ for men and >35″ for women, triglycerides ≥150 mg/dL, high-density lipoprotein cholesterol ≤40 and ≤50 mg/dL for men and women, respectively, blood pressure (BP) ≥130/85 mmHg, and fasting plasma glucose (FBS) ≥100 mg/dL.

The Food and Drug Administration (FDA) issued a black-box warning in 2003 regarding the risk of diabetes of SGAs.[9] Guidelines based on empirical evidence advocate for periodic monitoring. According to the American Diabetes Association/American Psychiatric Association (ADA/APA) guidelines, the patient's weight must be checked at 4-, 8-, and 12-week intervals after initiating or switching to SGAs and every 3 months thereafter during routine visits. Twelve weeks after the initiation of antipsychotic medication, blood sugar, lipids, and BP should also be examined. Subsequently, BP and glucose levels should be evaluated annually and the lipid panel every 5 years.[10] The Canadian Cardiovascular Society recommends annual monitoring of lipid levels in those at risk of cardiovascular events.[11] A summary of ADA/APA monitoring recommendations is provided in Table 1.

Table 1: Atypical antipsychotic metabolic syndrome monitoring recommendation by the American Diabetes Association/American Psychiatric Association[10]

Recommended interval	Family history	WC	Body weight	BMI	BP	FBS/ HbA1c	Lipids
Baseline	√	√	√	√	√	√	√
4 weeks	-	-	√	√	-	-	-
8 weeks	-	-	√	√	-	-	-
12 weeks	-	-	√	√	√	√	√
Quarterly	-	-	√	√	-	-	-
Annually	√	√	-	-	√	√	-
5 years	-	-	-	-	-	-	√

√ denotes that the monitoring of the corresponding parameter is recommended. BMI=Body mass index, WC=Waist circumference, BP=Blood pressure, FBS=Fasting plasma glucose, HbA1c=Hemoglobin A1c

Available data suggest that individuals suffering from mental illness often do not receive the proper metabolic screening before starting and/or throughout antipsychotic treatment.[12-14] In the Middle East, few studies have assessed the rate of compliance with metabolic monitoring guidelines. We also noticed that the available studies provided aggregate compliance rates without breaking them down into intervals. Metabolic screening of SGAs at each interval specified by the guidelines, as in our study, may shed some light on the monitoring methods and indicate where interventions may have the greatest impact. These interventions may include professional patient and health-care education to improve the monitoring of physical health. The aim of this study was to provide a detailed account of how often patients receiving SGAs are monitored for metabolic side effects in comparison with the intervals indicated by the guidelines. As far as we are aware, this is the first research of its kind in Saudi Arabia.

Materials and Methods

A retrospective analysis of medical records was conducted at two large psychiatric hospitals in the Eastern Province of Saudi Arabia (King Fahd Hospital of the University in Al-Khobar and the Eradah Complex in Dammam) between February 2021 and June 2021. The facilities handle approximately 105,000 annual outpatient clinic visits. The inclusion criteria were as follows: (1) patients taking SGAs; (2) patients who had been on medication for ≥1 year; (3) patients with schizophrenia, schizoaffective disorder, or bipolar disorder; (4) male or female patients; and (4) patients aged ≥18 years. Ethical approval was obtained from the Institutional Review Board (IRB) vide Letter No. IRB-UGS-2021-01-058 dated 18/02/2021 with a waiver of informed consent since there was no direct relation with human subjects in this study.

QuadraMed, the institutions' electronic medical record system, was used to identify eligible patients. We obtained data on outpatient visits from the medical records departments for the 6 months preceding the start of our investigation (February 2020–September 2020). We searched for diagnoses listed in the inclusion criteria using ICD-10 coding (F20.0–F20.9, F25.0–F25.9, F31.0–F31.9). A total of 6279 patients were identified. The medical charts were reviewed in two stages. During the first stage, the investigators looked for patients who met the specified inclusion criteria. A total of 4012 patients were found eligible for inclusion in our study. The study sample was then randomly selected

using research randomizer software (randomizer.org). We used Raosoft (Raosoft Inc., Gary Trujillo, WA, USA), an online software, to calculate the sample size. As our population size was 4012, the minimum sample size required for our study to reach a confidence interval of 95% was 353. We then conducted the second stage of chart review to collect the data from medical records of 350 patients.

The compiled data were entered into a Microsoft® Excel spreadsheet after rigorous chart review. The collected data included patients' characteristics such as age, gender, metabolic comorbidities (diabetes, HTN, and hyperlipidemia), psychiatric illnesses, psychotropic medications, vital signs, and laboratory values. All doctors' notes were evaluated for any extra monitoring values noted on the chart. Metabolic comorbidities were obtained through either a report from the patient or documentation in the medical report. All the required parameters such as WC (inch), body weight,[15] body mass index, BP, hemoglobin A1c (HbA1c), and lipid profile were monitored at each interval, as suggested by the guidelines. If a laboratory value or vital sign was reported within a month of the suggested time frame, it was considered a monitoring event. If an evaluated parameter came between two intervals that should have been examined 1 month apart, only the closest interval in time was credited. This gap was intended to accommodate difficulties in scheduling patients and noncompliance with scheduled appointments. We did not collect data on the values of each parameter (e.g., weight in kg, HbA1c in mmol), but rather on whether or not they were performed.

The primary outcome measure was the proportion of patients who had their metabolic parameters checked at predetermined intervals. Population characteristics, commonly prescribed antipsychotics, and metabolic syndrome prevalence were secondary study outcomes.

The Statistical Package for the Social Sciences (SPSS Statistics for Windows 10, Version 23, IBM Corporation, Armonk, NY, USA) was used for data analysis. Frequency and percentage were used to describe categorical variables and ongoing variables.

Results

This retrospective chart review included 350 patients, 226 of whom (64.6%) were men and 124 (35.4%) women. Of the patients, 69.4% (n = 243) were aged between 20 and 40 years, and 26.9% (n = 94) were aged between 40 and 60 years. Patients aged <20 years and >60 years comprised 10% and 0.3% of the sample, respectively. Based on the diagnoses, the number of cases was as follows: schizophrenia (n = 231), 66%; bipolar disorder (n = 89), 25.4%; and schizoaffective disorders (n = 30), 9%. In terms of illness duration, 47.1% (n = 165) of patients had been ill for <5 years, 50% (n = 175) for 5–10 years, and 2.9% (n = 10) for >10 years. Olanzapine was the most commonly used drug in 153 (43.7%) patients, followed by risperidone in 67 (19.1%) and quetiapine in 61 (17.4%). Fifty-five patients (15.7%) were taking two antipsychotic medications and nine patients (2.6%) were treated with triple antipsychotics. Invega was the most frequently used in triple therapy (0.9% of patients), and olanzapine was most frequently used in dual therapy (4.9% of patients). A summary of these findings is presented in Table 2.

In our study, 10.9% of patients (n = 38) had metabolic comorbidity. Of these, 52.6% (20/38) had diabetes, 55.3% (21/38) had dyslipidemia, and 47% (18/38) had HTN. The percentage of diabetic patients for whom the suggested monitoring protocol was not followed was 52.4% (11/21). In total, 44.4% (8/18) of hypertensive individuals were not monitored according to the recommended guidelines. Finally, for 55.2% (21/38) of the hyperlipidemic patients, there was failure to adhere to the recommended monitoring protocol. In our study, 157 (44.9%) patients were classified as obese. The majority of obese patients (89.8%, 141/157) were on mono-antipsychotic therapy; 9.6% (15/157) were on dual antipsychotic therapy, and only one (0.6%) was on triple antipsychotic therapy. Table 3 shows the percentage of patients with metabolic comorbidities for whom parameter monitoring at each recommended screening interval was not adhered to l. Table 4 displays a Chi-square (2) statistic indicating the relationship between monitoring adherence rate, the presence of metabolic comorbidities, and gender. We discovered a statistically significant relationship between nonadherence to monitoring and the presence (or development) of diabetes mellitus (DM) at the 5-year interval ($P < 0.001$), HTN at the 12-week ($P < 0.05$) and yearly ($P < 0.05$) intervals, and hyperlipidemia at the 5-year ($P < 0.05$) interval. Individuals with a history of DM, HTN, or dyslipidemia were more likely to have better monitoring of their parameters.

Approximately one-third of patients completed the baseline parameters (29.6%). Blood sugar was identified as the most performed baseline laboratory test in 38.9% of the patients. We also observed that BP was documented in 64.7% of the patients, whereas WC was only measured in 1.4%. In terms of age, we discovered that compliance with baseline monitoring was considerably better for patients aged 25–30 years but was the lowest for those <20 or >50 years. Table 5 shows the percentage of individuals for whom there was compliance with the recommended monitoring parameters at baseline.

Following the baseline, the ADA/APA recommends monitoring at intervals of 4, 8, and 12 weeks and yearly. The

number of patients who were monitored according to the recommendations was categorized as "full compliance," "partial compliance," or "noncompliance," as shown in Table 6. Noncompliance indicates that none of the interval parameters were completed, whereas partial compliance indicates that only some of the parameters were fulfilled.

Table 2: Characteristics of patients receiving antipsychotic medications (*n*=350)

Characteristics	*N* (%)
Age (years), mean±SD	34.9±18
Gender	
Male	226 (64.6)
Female	124 (35.4)
Diagnosis	
Bipolar disorder	89 (25.4)
Schizophrenia	231 (66.0)
Schizoaffective disorder	30 (9.0)
Comorbidities	
Obesity	157 (44.8)
Hypertension	18 (5.1)
Diabetes	20 (5.7)
Hyperlipidemia	21 (6.0)
Medications	
Olanzapine	153 (43.7)
Risperidone	67 (19.4)
Quetiapine	61 (17.4)
Paliperidone depot	3 (0.9)
Aripiprazole	18 (5.1)
Clozapine	27 (7.7)
Number of antipsychotics	
1 antipsychotic	286 (81.7)
2 antipsychotics	55 (15.7)
3 antipsychotics	9 (2.6)

SD=Standard deviation

Table 3: Percentage distribution of individuals with metabolic comorbidities "nonadherent" with the recommended monitoring interval (*n*=350)

Disease	Recommended interval				
	Baseline	4 weeks %	8 weeks %	Yearly %	5-years %
Diabetes mellitus	100	36.8	39.4	28.9	N/A*
Hypertension	100	66.6	61	44.4	N/A
Hyperlipidemia	100	57.1	52.4	42.9	82.4
Obesity	100	34.1	37.2	40.5	N/A

*Data NA. NA=Not available

Discussion

As far as we know, this is the first study on the Saudi population that looked at each interval to find out whether the guidelines were followed. Our findings demonstrate that most physicians did not follow the ADA/APA standards in monitoring antipsychotics. Most patients did not receive a proper assessment of metabolic parameters at the initiation or during the continuation of antipsychotics. We found that adherence to yearly monitoring was much lower than at baseline (mean percentage: 29.6% vs. 1.7%). Therefore, it appears that patients were better monitored at the initiation of antipsychotic treatment than during long-term use. Low compliance with the monitoring criteria also included vital signs and weight, in addition to laboratory tests. Weight was checked in only 25.2% of cases at baseline, which is much lower than what was found in a study conducted in India (60%).[16] This leads us to conclude that the importance of metabolic monitoring should be underlined to both nurses and physicians since they are responsible for checking and documenting vital signs, WC, and weight. In our study, WC was checked at baseline in only 1.4% of cases, which accords with a similar study.[16] In many outpatient clinics, measuring WC was not routine. Considering that many psychiatric medications result in weight gain, we emphasize the importance of combining WC assessments with vital signs.

Unfortunately, only one-third of those surveyed in our study completed the baseline parameters, which is lower than in other countries.[9,16,17] In addition, 10.9% of the patients had metabolic comorbidity. Although blood glucose level was the most commonly performed baseline laboratory test in our study (38.9%), it was significantly lower than in studies conducted in other countries such as the United States (54%)[17] and India (47%).[16] Only 17% of the patients had their lipid panels monitored at the initiation of antipsychotic treatment. Although olanzapine is one of the most prevalent SGAs that cause weight gain, we discovered that it was the most commonly used drug in our sample (39.5%).

Table 4: Chi-Association between rate of adherence to monitoring, presence of metabolic comorbidities, and gender difference among patients receiving antipsychotic medications (*n*=350)

Disease	Recommended interval									
	4 weeks		8 weeks		12 weeks		Yearly		5-year	
	χ^2	*P*-value	χ^2	*P*-value	χ^2	*P*-value	χ^2	*P*-value	χ^2	*P*-value
Diabetes mellitus	3.027	0.220	0.963	0.618	3.188	0.203	4.216	0.122	20.536	0.000**
Hypertension	3.436	0.179	1.925	0.382	7.971	0.019*	6.108	0.047*	8.870	0.064
Hyperlipidemia	4.421	0.110	2.527	0.283	3.139	0.208	2.131	0.531	11.772	0.019*
Gender	8.589	0.011*	1.268	0.530	1.21	0.494	7.746	0.101	4.073	0.667

*P<0.05, **P<0.001. χ^2=Pearson Chi-square

Table 5: Percentage distribution of patients receiving antipsychotic medications adherent with a recommended monitoring parameter at baseline (*n*=350)

Intervention	Compliance %	Noncompliance %
FBS or HbA1c	38.9	61.1
Lipid panel	17.3	82.7
BP	64.7	35.3
Weight	25.2	74.8
WC	1.4	98.6
Height	30.3	69.7
Average percentage for all parameters	29.6	70.3

BP=Blood pressure, FBS=Fasting plasma glucose, HbA1c=Hemoglobin A1c, WC=Waist circumference

Table 6: Percentage distribution of patients receiving antipsychotic medications compliant with recommended monitoring parameters at follow-ups (*n*=350)

Recommended interval	Noncompliance *N* (%)	Partial compliance *N* (%)	Full compliance *N* (%)
Week 4	208 (59.4)	0	142 (40.6)
Week 8	254 (72.6)	0	96 (27.4)
Week 12	263 (75.1)	53 (15.1)	34 (9.7)
Yearly	236 (67.4)	108 (30.9)	6 (1.7)

We hypothesize a few reasons for the low compliance during the period of follow-up. The most obvious is that doctors often forget to order the tests promptly because the guidelines for each parameter have different requirements at different intervals. In addition, the complexities of the guidelines in which the monitoring intervals are irregular are one of the most probable causes of unsatisfactory compliance because of the difficulty in memorizing it. In the survey by Mangurian *et al*., of 160 primary care physicians (PCPs) in a community health setting, as many as 40% of the PCPs were found to be unaware of the monitoring guidelines.[18] Helping practitioners recall the required laboratory tests and vitals at certain intervals could help improve metabolic monitoring practices. Ideally, the electronic medical system should correctly identify the timeline of parameter evaluation to alert the physician.

A study conducted in the United Kingdom found that only a small percentage of individuals underwent regular monitoring of glucose (7%), BP (2%), WC (0%), weight (0%), and lipid panel (4%).[19] Poojari *et al*'s clinical audit of 668 patients in an Indian hospital reported that only 47% of the patients had their blood sugar checked at baseline and every year.[16] In addition, in a research by Peña *et al*., compliance with baseline weight monitoring was for 28% of the subjects only.[17] An additional research study examination of the degree of metabolic monitoring of antipsychotic-prescribed outpatients in Malaysia revealed a low frequency of metabolic parameter recordings.[14]

The present study has certain limitations. First, since it was a retrospective study, it is possible that all relevant data may not have been found owing to deficient documentation in the case files. Assuming that the lack of documentation of results means there was no monitoring, this study indicates the extent to which metabolic monitoring parameters have been documented. In addition, nonadherence cannot be blamed on the physician because the physician could have ordered the testing, but the patient might have skipped the laboratory test. Finally, we did not study the barriers to metabolic monitoring in patients with serious mental illnesses. Future studies are required in Saudi Arabia to explore the barriers of adherence to the monitoring guidelines. Many studies have described hurdles to monitoring adverse metabolic effects in patients taking antipsychotics. The challenges in managing the cardiovascular and metabolic conditions of patients using antipsychotic medications are believed to be multidimensional.[13] Barriers have been linked to healthcare providers, health-care systems, patients' families, and the patients themselves. The following reasons have been reported repeatedly in various studies: poor coordination among health-care providers, a lack of knowledge and training of health-care providers to manage physical health issues, insufficient physician time, fragmentation of care, a lack of resources to manage a healthy lifestyle, staff turnover, a lack of support from family/friends, and mental health condition-related disabilities such as the severity of psychotic symptoms.[18,20-33]

Conclusion

The main findings demonstrate that the metabolic parameters of a large percentage of patients in our study were not properly assessed prior to starting or during the continuation of SGAs. The lack of metabolic monitoring in this population is concerning because of the well-documented risks of endocrine, metabolic, and cardiovascular adverse effects. This underlines the importance of health-care practitioners reevaluating their existing metabolic monitoring processes for this population in order to identify those at risk of metabolic syndrome early. The results of this research urge health-care systems to identify difficulties in performing routine metabolic monitoring of patients treated with antipsychotics. Barriers to adherence to the monitoring guidelines should be examined and addressed.

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Conflicts of interest

There are no conflicts of interest.

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