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INCIDENCE OF PSYCHOTROPIC DRUGS PRESCRIBED IN CHILDREN AND ADOLESCENTS WITH AUTISM AT EL. TEGANI-ALMAHI REFERENCE HOSPITAL KHARTOUM SUDAN. A CROSS-SECTIONAL STUDY.

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Abstract:

Background:

Autism spectrum disorder (ASD) among vulnerable populations frequently presents with complex mental health diagnoses, and psychotropic medications are often a component of comprehensive biopsychosocial treatment plans for these conditions. The primary aim of this study is to determine the incidence of usage of psychotropic drugs and to assess the response of psychotropic medications prescribed in children and adolescents with autism in a resource-constrained setting in Khartoum Sudan.

Materials and methods:

Following an institutional review board approval, Department of Innovation, Development and Scientific Research, Ministry of Health, Khartoum State (IDSREC-2020-EATA/44/A), A cross-sectional retrospective hospital-based study was conducted from January 2018 to Jan-2021 among 261 children and adolescents aged 1 to 17 years diagnosed with ASD using The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR) as a guideline. SPSS version 25.

Results:

The prevalence of ASD was greater in males than females; 45% of autistic patients have at least one comorbid disease. Attention Deficit Hyperactivity Disorder (ADHD), learning disability (LD), and epilepsy are the three most comorbid diseases among autistic patients. The Average number of psychotropic drugs per prescription was 1.8 out of 2.61. The most often prescribed medications among this group were risperidone (49%), methylphenidate (33%), and valproic acid (15%). All the patients received at least one psychotropic prescription; 30% of the patients were receiving polytherapy. Non-adherence of the patient to their medication account for 24%. This indicated the efficacy of other treatment approaches and the importance of combining medication and non-medication therapy.

Conclusion:

The study revealed a significant use of psychotropic medication, with a notable emphasis on antipsychotics. There is a high incidence of prescription rates for psychotropic medications for comorbid psychiatric disorders.

Keywords: *Autism, Psychotropic, Drugs, Epilepsy, Psychiatric disorder, mental health, prevalence, prescription.*
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Introduction:

Autism Spectrum disease (ASD) is a severe and lifelong neurodevelopmental disease that has substantial social costs and a significant impact on the quality of life for patients and family members. (1) Even though this disease may last a lifetime, some services and therapies can help with symptoms and day-to-day functioning. The American Academy of Pediatrics suggests that all children be screened. Parents and caregivers should consult their children's doctors about ASD screening or evaluation. (1) ASD is a condition related to brain development that affects how a person perceives and socializes with others, causing problems in social interaction and communication. The term "spectrum" in ASD refers to a wide range of symptoms and severity. (2) Owing to the complexity of ASD and the fact that its symptoms and severity vary, there is no single

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recognized etiology for the illness. Factors from both nature and nurture contribute to this illness. (3). several genes appear to be involved in autism development. In some children, ASD can be associated with a genetic disorder such as Rett syndrome or fragile X syndrome. Some genetic mutations seem to be inherited and play a role in ASD, the use of thalidomide or valproic acid by the birthing parent during pregnancy, early labor and delivery, problems during delivery, and low birth weight are among the linked risk factors for ASD. The birthing parent must be 35 years old or older. (3) However, increased use of psychotropic medications is a topic of debate among professionals and the public (4). The prevalence and patterns of medication use in individuals with ASD have been investigated in several countries. Parents indicated that 24.6% of 65 children used psychotropic medications, and antipsychotics were the most commonly used, followed by stimulants, antidepressants, and mood stabilizers (5). The US Food and Drug Administration-approved medications for ASD are risperidone and aripiprazole, for the treatment of irritability (6, 7), psychotropic medications are prescribed to about 30%–60% of Children with ASD to regulate their anger, impatience, and other undesirable behaviors. (8, 9). The patterns of management approaches for ASD include behavior and communication therapies, educational therapies, family therapies, speech therapy, occupational therapy, physical therapy, and medications. Medication therapy involves the use of psychotropic drugs according to the primary therapeutic effects and mental health disorders (10). The psychotropic drugs used in ASD include antidepressants, anxiolytics, antipsychotics, and mood stabilizers (11). Psychotropic medications are a class of drugs that are used to treat mental health disorders (12). Sertraline and escitalopram were prescribed as antidepressants. Benzodiazepines and beta-blockers are commonly used as anxiolytic and antidepressant medications. Aripiprazole and asenapine are commonly used antipsychotics. Lithium, valproic acid, and lamotrigine are commonly used mood stabilizers (13). However, no pharmacological agents have proven to be effective against the core symptoms of ASD (14, 15). The drugs mainly target comorbid symptoms associated with ASD, such as irritability, and psychiatric comorbidities, such as attention deficit hyperactivity disorder and obsessive-compulsive disorder (OCD) (14, 15). Except for a few antipsychotics approved for the treatment of severe behavioral problems (irritability) in ASD (16) psychotropic drugs are used off-label According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (16). In a study of 60,641 children with ASD, 56% of child patients were reported to have received prescriptions for one or more psychotropic medications (17, 18). Therapies and interventions are often different for each person (19). Research has shown that early diagnosis and intervention, especially during preschool, are more likely to have positive effects (2). Treatment must focus on a person's specific needs rather than the diagnostic label (19). Behavioral management therapy attempts to reinforce desired behaviors and reduce unwanted ones. Behavioral therapy is often based on applied behavior analysis (ABA) (19). Complications of ASD include feeding problems, restless nights, and digestive issues (GI issues). Seizures, ADHD, depression, and anxiety Additional mental health issues include bipolar disorder, schizophrenia, and obsessive and compulsive disorder (OCD) (20).

The objective of this study was to evaluate the patterns of psychotropic drug prescriptions in children and adolescents diagnosed with autism spectrum disorder (ASD) at the El Tegani-Almahi Reference Hospital in Khartoum, Sudan. By examining prescribing practices, this research aims to contribute to the understanding of treatment approaches and potentially improve the clinical management of ASD within the Sudanese healthcare context.

Materials and methods:

Following an institutional review approval from, the Department of Innovation, Development, and Scientific Research, Ministry of Health, Khartoum State (IDSREC-2020-EATA/44/A), a cross-sectional retrospective hospital-based study was conducted from January 2018 to January 2021. Out of 625 patients assessed, 261 children and adolescents aged 1 to 17 years were diagnosed with ASD using the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR) published by the American Psychiatric Association as a diagnostic criterion. These criteria include a deficit in social communication and interaction, restricted repetitive patterns of behavior and interest or activities, symptoms that must be present in the early developmental period, and clinically significant impairment due to symptoms. Patient-related information such as gender, age, diagnosis, and drug-related information (Average number of the psychotropic drugs prescribed per prescription; Percentage of the psychotropic drugs prescribed) were extracted from the PACS and exported to an Excel sheet. The data obtained were analyzed using SPSS version 25 where statistical measures such as mean, Frequency, and percentages of any psychotropic medication used were indicated and the adherence versus response cross-tabulation was obtained.

Study design:

Cross-sectional retrospective hospital-based.

Study setting:

El. Tegani-Almahi reference hospital Khartoum Sudan. The study was conducted from January 2018 to January 2021.

Study population:

Children and adolescents aged 1-17 with Autism male and female.

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Sample size:
Total coverage (All) patient files with autism from Jan 2018 to Jan 2021

Data measurement/ collection:
All children and adolescents whose diagnoses follow the DSM-5-TR. The data collection was extracted from the PACS and exported to an Excel sheet, and each sheet had a specific number.
Statistical methods: the data obtained were analyzed using SPSS version 25

Ethical consideration:
This study was conducted in strict adherence to ethical guidelines and approved by the relevant ethical review board at the Department of Innovation, Development, and Scientific Research and El Tegani-Almahi Reference Hospital. All patient data was handled with the utmost care and confidentiality. Informed consent was obtained from the guardians of all participants involved in the study, and all procedures were conducted according to the ethical principles outlined in the Declaration of IDSREC.

Informed consent:
Informed consent was obtained from all subjects involved in the study.

Inclusion and exclusion criteria:
The study includes all children and adolescents with ages below 17 years during carrying this research between the years of 2018-2021. The study excludes all children and adolescents whose diagnoses do not follow the DSM-5-TR.

Result:
The prevalence of ASD was greater in males than females; 45% of 118 patients with autism had at least one comorbid disease. Attention Deficit 119 Hyperactivity Disorder (ADHD), learning disability (LD), and epilepsy are the three 120 most common comorbidities in patients with autism. The mean number of 121 psychotropic drugs prescribed was 1.8 2.61. The most frequently prescribed drugs 122 among this group were risperidone (49%), methylphenidate (33%), and valproic 123 acid (15%). All patients received at least one psychotropic prescription, and 30% of patients received polytherapy. The non-adherence rate of patients to their 125 medications was 24%. This indicates the efficacy of other treatment approaches 126 and the importance of combining medication with non-medication therapy.

Table 1. Demographics data of total participants

GENDER	FREQUENCY	PERCENT
Male	225	86.2%
Female	36	13.8%
Age (years)		
1–6	130	49.8%
7–12	91	34.9%
13–17	40	15.3%
Total	**261**	**100%**

Table 2. Incidence of psychotropic drug prescribed, autism, and autism with other comorbid disease

Incidence of psychotropic drug-prescribed		
	Frequency	**Percent**
Medication only therapy	186	71.3
Medication and other therapy	75	28.7
Total	**261**	**100**
Incidence of autism and autism with other comorbid diseases		
	Frequency	Percent
Autism only	142	54.4
autism with ADHD	54	20.7%
Autism with a learning disability	39	14.9%
Autism with epilepsy	14	5.4%
Autism with psychosis	12	4.6
Total	**261**	**100**

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*** Other medication therapy*

- *Behavioral therapy* **speech therapy* **family therapy*
- *Psychotherapy*

Table 3: Percentage of most commonly psychotropic medications used per prescription and the adherence versus response

Medicine	Frequency	Percent
risperidone	128	49.4%
methylphenidate	86	33%
valproic acid	51	15%
sedatives	32	12.5%
Carbamazepine	24	9.3%
Other antipsychotics	12	5.1%
Total	**261**	**100**
Adherence versus response cross-tabulation		
type	Frequency	Percent (%)
Adherence	207	79.3
Non-adherence	54	20.7
Total	**261**	**100**

Figure 1. Incidence of disease rate among the age group

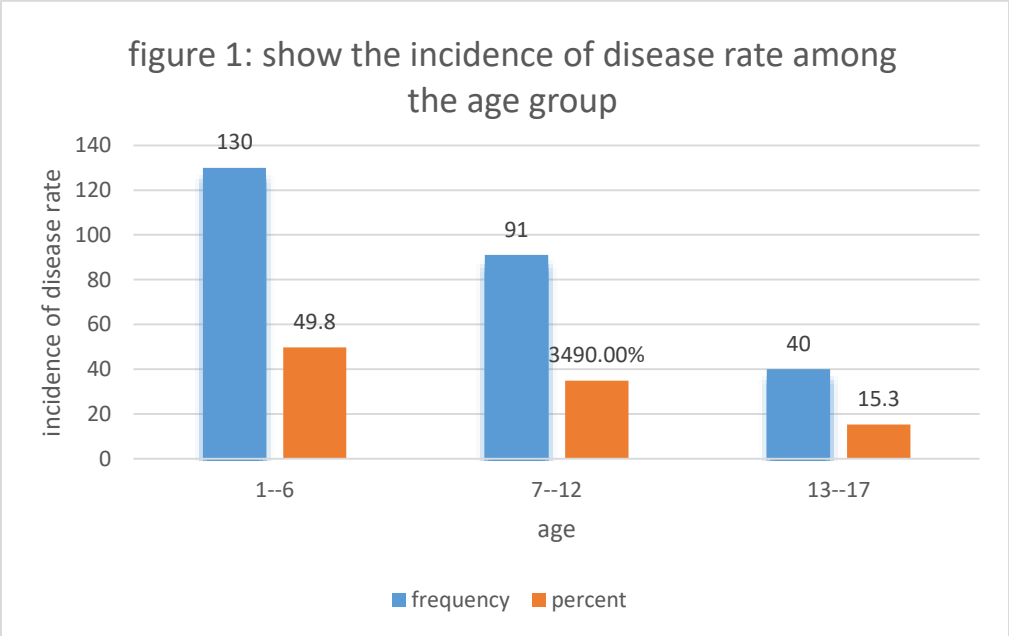

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Table 4 Adherence * response cross-tubulation

Adherence		Response		Total
		Responded	Not Responded	
Adherence	count	171	36	207
	% within response	81.4%	70.6%	79.3%
Non-adherence	count	39	15	54
	% within response	18.6%	29.4%	20.7%
Total	count	210	51	261
	% within response	100%	100%	100%

Potential eligible participants: 390 children and adolescents with autism based on initial screening of the medical records, the participants who met all inclusion criteria (age, autism diagnosis, and at least one psychotropic drug were confirmed as eligible.

Included in the study:

261 participants were enrolled in the final survey, and their medical records were used for the incidence of psychotropic drugs.

Follow diagram:

1. Potential eligibility: (390) 31 non-ASD diagnoses, 46 Age outside criteria =313 examined for eligibility.
2. Examined for eligibility: 317 18 incomplete records, 23 no psychotropic medication=276 confirmed eligibility.
3. Confirmed eligibility: 276 15 co-occurring primary psychiatric disorders = 261 included in the study.

Discussion:

Papers in Autism, the median age of cases was 8.5 years, with a range of 1.3 to 17 years. The majority of patients received psychotropic medications, and rates were much higher among young children. Rates compare with reports in the literature ranging from 33% to 83%. The high predominance of children under age 5 explains the incidence of prescribing rate increase in the last years. Rates of medication use in these older groups are similar to other reports in the literature. This study found that males were significantly more often diagnosed and were more often prescribed drugs than were females with 86.2% of the total, The predominance number of patients diagnosed with ASD in ages 1–6 and 7–13 years age groups as shown in percentage 49.8% and 34.9% while the minority between 13 to 17 which is 15.3%, males showed a higher prescription rate than females.

Some studies reported no relationship between gender and the prevalence of psychotropic use (25-27), 45% of autistic patients have at least one comorbid disease. 20.7% ADHD, followed by 14.9% learning disability and 5.4% epilepsy, the three most common diseases comorbid with autism. According to one study, 70% of people with ASD have at least one comorbid psychiatric condition (28).

A prior study found that children with ASD have an average of 2.54 drugs per individual, Comorbid psychiatric problems can account for up to 70% of pharmacological prescriptions. (29). In this study the Average number of psychotropic drugs per prescription was 1.8 and Compared to the general population, children with ASD use overall seven times more psychotropic drugs, including 15 times more antipsychotics and four times more ADHD medications .in this study, the most often frequently prescribed drugs among this group were risperidone (49%), followed by methylphenidate (33%) and valproic acid (15%) in order, these findings were similar to the results of previous studies conducted based on medical aid claims data

Regarding antipsychotic medications, stimulants, such as methylphenidate and amphetamines, are commonly prescribed for ADHD, making them the most frequently utilized psychotropic medications among children.

All autistic children and adolescents received at least one psychotropic prescription and 30% of the patients were receiving polytherapy. The adherence of autistic patients without the comorbid disease to their medication is higher by 18.6% than autistic with other comorbid diseases, and 24% of non-adherence patients showed improvement in the symptoms which indicated the efficacy of other treatment approaches and the importance of combined medication therapy to non-medication therapy. 28.7% of the patients received Medication and other therapy approaches and 71.3% had received Medication-only therapy. Further research is needed to investigate the long-term results, the effectiveness of various treatments, and the possible role of local healthcare policies in optimizing care for children with ASD.

The results are summarized in this conclusion, which highlights the significance of balanced treatment modalities and recommends areas for additional studies and policy development.

The study's findings indicate that psychotropic medicines, particularly antipsychotics and stimulants, are often prescribed in this population, presumably reflecting the treatment of a variety of psychiatric problems. The high prescription rates for people with comorbid psychiatric disorders point to a complex clinical picture in which

various mental health conditions are treated concurrently. This could indicate an increasing requirement for comprehensive care solutions that address both primary and co-occurring psychiatric illnesses. The dependence on these medications emphasizes the significance of monitoring their consumption, assessing potential side effects, and investigating alternative or supplementary treatments to ensure successful and holistic care of patient's mental health.

Limitations:

Sampling bias: The study may have been done on a specific population or geographical area, limiting the findings' applicability to larger or more diverse populations.
Confounding Factors: Other variables, such as socioeconomic position, access to healthcare, or concurrent medical issues, may have been impacting the study's findings. This study is a secondary data analysis with a limited sample size, there are few comparable research in Sudan with which to compare our findings. The cross-sectional approach limits our capacity to generalize our findings to families of children with ASD.

Conclusion:

There is a high incidence of prescription rates for psychotropic medications for comorbid psychiatric disorders. The research revealed significant use of psychotropic medication among this population, with a notable emphasis on antipsychotics and stimulants. These drugs are primarily prescribed to manage behavioral symptoms associated with autism, including aggregation hyperactivity, and irritability. The study also underscores concerns about the lack of standardized guidelines in prescribing practice, the potential side effects of long-term psychotropic drugs used in children and adolescents, and the limited availability of alternative therapeutic interventions, such as behavioral.

Recommendation:

1. Create clear medication use guidelines
2. Prioritize non-pharmacological interventions
3. Personalized Medicine Approach.
4. Complete Monitoring of Medication Efficacy and Side Effects
5. Enhance parent and caregiver education.
6. Conduct additional research on the long-term effects of psychotropic medications.

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List of abbreviations:

ABA: applied behavior analysis
ASD: Autism spectrum disorder
ADHD: Attention Deficit Hyperactivity Disorder
DSM-5-TR: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision
IDSREC: Department of Innovation, Development and Scientific Research, Ministry of Health, Khartoum State
LD: Learning disability
OCD: obsessive-compulsive disorder

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Conflict of interest statement:

The authors declare no conflict of interest

Author contributions:

Alrazi Eisa Shogar1, the conceptualization of the study, study design, data collection, analysis, and writing the manuscript.
Mohammed Elhassan Shayoup2 provides a critical revision to the study.
Mohammed Sani Umer3 contributed to the manuscript writing.

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