

# A Drug Utilization Study of Psychotropics Prescribed for Children and Adolescents in a Tertiary Care Hospital of Eastern India

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## Abstract

There is growing trend of psychiatric morbidity among children and adolescents all over the world. Medications are prescribed to this age group mainly depending on data obtained from adult population. Proper study to find out exact burden of the problem and the effects of these drugs to young population has not been done in our part of the world. The study was done to identify the incidence of different psychiatric problems with the most common pharmacotherapy given in children and adolescents. It is a cross sectional observational study conducted in the Psychiatry OPD of Medical College Kolkata by the department of Pharmacology from May 2014 to October 2014. After institutional ethics committee approval and consent from guardians, 86 patients of either sex were included in the study. Patient demographics (gender distribution, age of the patients, diagnosis) and drug-related information (antipsychotic drugs, route of administration) was recorded on a customized data collection sheet. Data was analysed using descriptive statistics. 61.9% in children and 67.69% in adolescent age group were boys. Mood disorder, mental retardation and epilepsy are 3 major diagnosis encountered. Average number of psychotropic drug per prescription was  $1.41 \pm 0.8$ . 91.73% drugs were prescribed by generic name. 80.16% of the drugs supplied from hospital pharmacy. Antidepressants (29.75%) most commonly prescribed followed by Antipsychotics (26.44%). 30% patients were receiving polytherapy. We found 1-18 year age group was common in psychiatry OPD. Most common diagnosis was behavioural and neurotic disorders, while the most commonly prescribed drugs were antidepressants and antipsychotics.

**Key words:** Psychotropics, Drug Utilization, polytherapy, children, adolescents.

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## INTRODUCTION

There is a growing concern about the increasing number of children and adolescent who use psychotropic medication. According to World Health Organisation report the worldwide burden of psychiatric morbidity in children and adolescent is about 20% [1]. Psychiatric illness in this  $\leq 18$  years of age group is a serious problem in India because more than 40% of our population is  $\leq 18$  years of age [2]. Major concerns involve the lack of evidence regarding safety and efficacy of the majority of psychotropic agents in children, in particular during long-term treatment and the possible overprescribing [3,4]. Studies which have been based on the prescription claims data, the pharmacy dispensing data and on surveys on the general population have shown a trend of increasing psychotropic drug prescription in this age group [5, 6]. The increase in the medication use has not been accompanied by an increase in the clinical research which evaluates the efficacy of these drugs in the

population. The clinical experience and the adult psychopharmacology data have added on to the limited information on the psychotropic drug use in children. However, the emergence of data which has questioned the safety of the selective serotonin reuptake inhibitors (SSRIs) in young people has highlighted the need for well conducted research in children and adolescents [7]. Also, given the considerable public health relevance of drug safety in children, and the potential effects of psychotropic medications on their physical growth and brain development, it is important to identify valid methods for detecting the possible drug-induced adverse events during an early or prolonged exposure to the drugs [8]. Before the issues which are related to excessive psychotropic drug use are addressed, it is essential to determine the actual rates of medication use and the clinical context of their use. Most of the research regarding psychotropic drug use in the paediatric and adolescent age group has been conducted in the United States or Europe and studies have shown

that the patterns of prescribing and drug utilization vary internationally and within regions [9]. Very few researches have examined the patterns of the psychotropic drug utilization in children and adolescent in India. Therefore, this study was undertaken to identify the pattern of the psychiatric illness and the psychotropic drug utilization in children and adolescents who were attending the psychiatry outpatient departments.

## MATERIALS AND METHODS

An observational cross sectional study was carried out in outdoor patients (OPD) of the Psychiatry department of Medical College and hospital, Kolkata. Duration of study was 6 months. Permission of the Institutional Ethical Committee was obtained for conducting the study. Subject recruitment commenced only after such approval was obtained in writing. Informed written consent was taken from the legally acceptable representative of each participant. Illiterate legally acceptable representative will give their fingerprint (left thumb impression) instead of signature in the presence of an appropriate witness. Patients of paediatric and adolescent ages of both sexes were

included in the study. Indoor-patients, referred patients and Patients having no legally acceptable guardian were excluded from the study. Patient related information (gender distribution, age of the patients, diagnosis) and drug-related information (antipsychotic drugs, route of administration) were recorded on a customized data collection sheet. Total 86 cases were analyzed. The WHO drug indicators were selected to analyze the prescribing pattern: (1) Average number of the psychotropic drugs prescribed per prescription, (2) Percentage of the psychotropic drugs prescribed by generic name, (3) Percentage of the psychotropic drugs prescribed from national list of essential medicine – 2011, (4) Frequency of psychotropic drugs prescribed in injectable form, (5) Percent of psychotropic drug prescribed from hospital pharmacy.

## RESULT AND ANALYSIS

In a six months period from May 2014 to October 2014, a total of 86 patients were included in the study and their prescriptions containing at least one antipsychotic were analyzed only once time – no follow up visit was done.

**Table-1: Distribution of demographic parameters and morbidity patterns**

AGE DISTRIBUTION	No. of patients (n= 86)	Boy	Girl
Children (1 - 9 yrs)	21 (24.41 %)	13 (61.90 %)	8 (38.10 %)
Adolescents (10 - 18 yrs)	65 (75.58 %)	44 (67.69 %)	21 (32.31 %)
<b>DIAGNOSIS</b>			
Mood disorders	16 (18.60 %)	8	8
Mental Retardation	15 (17.44 %)	8	7
Epilepsy	12 (13.95 %)	7	5
Anxiety	9 (10.46 %)	6	3
Obsessive Compulsive Disorder	9 (10.46 %)	3	6
Psychosis	7 (8.13 %)	3	4
Conversion disorder	6 (6.97 %)	2	4
Migraine	4 (4.65 %)	1	3
Adjustment disorder	3 (3.48 %)	3	0
Enuresis	1 (1.16 %)	0	1
ADHD	1 (1.16 %)	1	0
No diagnosis	3 (3.48 %)	-	-

Table 1 shows among the 21 children (aged between 1 to 9 years) attended the OPD, 61.9 % (13/21) were boy and 38.1% (8/21) were girl. 65 adolescents (aged between 10 to 18 years) also attended the OPD by this time, among which 67.69 % (44/65) were boy and 32.31% (21/65) were girl. The common primary

diagnosis is also shown in Table 1. Overall disorders of psychological development are common in males and neurotic disorders are common in females. Mood disorders and behavioural disorders are almost similarly occurring in both genders.

The mean age of boys in this age group were  $3.23 \pm 2.84$  years and mean age of girls in this age group were  $3.75 \pm 3.24$  years. The mean age of

adolescent boys were  $13.79 \pm 2.18$  years and girls were  $12.8 \pm 2.11$  years (Table 2).

**Table-2: Distribution of average age of patients**

Average age of boys in age group of 1 – 9 years (mean $\pm$ SD)	$3.23 \pm 2.84$
Average age of girls in age group of 1 – 9 years (mean $\pm$ SD)	$3.75 \pm 3.24$
Average age of boys in age group of 10 – 18 years (mean $\pm$ SD)	$13.79 \pm 2.18$
Average age of girls in age group of 10 – 18 years (mean $\pm$ SD)	$12.8 \pm 2.11$

## Analysis of prescription patterns according to WHO drug use indicators

Table-3: Prescribing indicators

Average number of psychotropic drug / prescription	1.41 ± 0.8
Percentage of the drugs prescribed by generic name	111/121 (91.73 %)
Percentage of the drugs prescribed from NLEM 2011	83/121 (68.59 %)
Percentage of the drugs supplied from hospital pharmacy	97/121 (80.16 %)
Frequency of psychotropic drugs prescribed in injectable form	5/121 (4.13 %)

Table 3 summarizes prescribing indicators according to WHO. A total of 86 prescriptions containing 153 drugs were analyzed. Of these, 121 were psychotropic drugs. The other co-prescribed drugs were antacids, multivitamins and iron and zinc preparations. Average  $1.41 \pm 0.8$  antipsychotic drugs were prescribed per prescription with 91.73% in generic name and rest

were branded. 68.59% were from National List of Essential Medicines of India (NLEM), [10]. Percentage of prescriptions with injectable drugs accounted for 4.13 % and the hospital pharmacy has supplied 80.16 % of prescribed drugs. 70% patients received monotherapy and 30% patients received polytherapy as shown in figure 1.

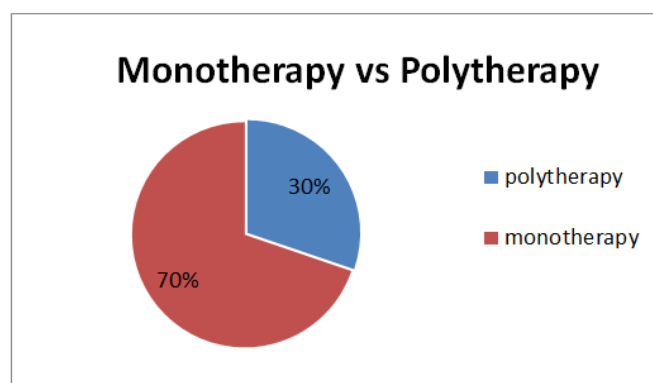


Fig-1: Shows Prescription Pattern either Mono-Therapy or Poly-Therapy

Table-4: Drug related informations

Drug Class	Drug	No of drug (n=121)	Percentage (%)
Antidepressants (29.75%)	Sertraline	17	14.05
	Fluoxetine	8	6.61
	Escitalopram	7	5.78
	Others	4	3.31
Antipsychotics (26.44%)	Risperidone	13	10.74
	Olanzapine	10	7.44
	Haloperidol	4	3.31
	Others	5	4.13
Anticonvulsants (18.18%)	Phenytoin	6	4.96
	Divalproex-Na	6	4.96
	Levetiracetam	3	2.47
	Oxcarbazepine	3	2.47
	Phenobarbital	2	1.65
	Others	2	1.65
Mood stabilizer (9.91%)	Lithium	9	7.44
	Carbamazepine	3	2.47
Sedative-Anxiolytics (8.26%)	Clonazepam	6	4.96
	Lorazepam	2	1.65
	Others	2	1.65
Other drugs (10.74%)	Methylphenidate	5	4.13
	Trihexyphenidyl	2	1.65
	Cyproheptadine	1	0.83
	Desmopressin	1	0.83

Table 4 indicates in this under-18 year age group majority of the patient received antidepressants and antipsychotics as psychotropic drug. Atypical antipsychotics like risperidone (10.74%) and olanzapine (7.44%) are common among antipsychotics whereas SSRI like Sertraline (14.05%), Fluoxetine (6.61%) and Escitalopram (5.78%) are common among antidepressants. Anticonvulsants, mood stabilisers and anxiolytics are observed as other frequently used drugs among these children and adolescent age group. Among these frequently used drugs were Lithium (7.44%), clonazepam (4.96%), phenytoin (4.96%), di-valproex Na (4.96%) and Methylphenidate (4.13%).

## DISCUSSION

The burden of illness on children and adolescent resulting from psychiatric and behavioral disorders is enormous, although it grossly remains under represented by conventional public health statistics. However, to date limited information about the psychotropic drug use in the population of eastern India is available. This study examined the patterns of psychotropic medication utilization in children and adolescent in our hospital.

There was no significant difference in the age presentation of both the genders in children and adolescent age group, a trend which was similar to that which was found in other studies [11,12]. In children 61.90% and in adolescent 67.69% of the total study subjects were male in our study, as compared to a range of 44.3% to 52.5% in other studies [11,12].

The lower percentage of females encountered in our study was possibly due to the social stigma in India and the reluctance of the parents to present females to the psychiatrists [13].

Mood disorders, mental retardation, epilepsy, neurotic, stress related and somatoform disorders, behavioural and emotional disorders were the most common diagnoses. Overall disorders of psychological development are common in males and neurotic disorders are common in females. Mood disorders and behavioural disorders are almost similarly occurring in both genders. This pattern was consistent with that of similar studies which were done in India [14].

Different studies reports different prescription rates of various groups of drugs. In our study the percentage use of the drug classes was as follows – antidepressants – 29.75%, anti-psychotics – 26.44%, antiepileptics – 18.18%, mood stabilizers – 9.91%, anxiolytics – 8.26% and others – 10.74%. In the study done by Dean *et al.* the percentage use of antidepressants was 56.6%, antipsychotics was 32.8%, anxiolytics/hypnotics was 13.9%, stimulants was 13.9%, and mood stabilizers was 3.3% [11]. However, the drug utilisation rate difference may be due to

difference in disease presentation pattern. Selective serotonin reuptake inhibitors were the most commonly prescribed antidepressants. This finding was similar to other studies, both among children and in adults [5, 15]. Sertraline (14.05%) was most popularly prescribed SSRI. The reason could be that Sertraline have a more favourable pharmacokinetic profile and fewer pharmacokinetic drug interactions than other SSRIs [16]. Fluoxetine (6.61%) and Escitalopram (5.78%) are the other commonly used SSRI antidepressants. The high usage and familiarity with these agents in adult psychiatry may be the cause for their greater use in the paediatric and adolescent age group. In our study, most of the patients who received anti-psychotics were on atypical anti-psychotics and risperidone (10.74%) was the most commonly used atypical antipsychotic, followed by olanzapine (7.44%). There is very few evidence to support the current practices which involve the paediatric use of antipsychotics, except for a few short term studies [17, 18]. Atypical anti-psychotics are popularly used due to their lower incidence of the extrapyramidal side effects, but the side effects, including extrapyramidal effects, may occur more frequently in younger patients as compared to the adults [19]. Currently, there is insufficient evidence regarding the potential consequences of weight gain and the endocrinological changes associated with long term use of the atypical antipsychotics [18]. Larger, detailed studies are needed to confirm these observations. The proactive monitoring of the body weight, fasting blood glucose and the lipid levels is necessary for taking into consideration the developmental norms that incorporate the age- and sex-specific thresholds [20]. Among the anticonvulsants phenytoin and valproate/ divalproex-sodium were used more frequently, mostly due to their wide range of effectiveness. Newer drugs like levetiracetam and oxcarbazepine are also used as monotherapy. While in some cases the newer antiepileptic drugs have a more favourable pharmacokinetic and toxicity profile than the older drugs, there appears to be no objective evidence that any currently available antiepileptic drug is superior in terms of therapeutic efficacy [21]. Lithium was the most commonly used drug for bipolar disorder in our study, followed by carbamazepine. Other study also supports use of lithium as most commonly used medication for paediatric bipolar disorder, but there are no well controlled large studies which have evaluated the efficacy of anticonvulsants [22]. In our study, clonazepam was the most frequently used anxiolytic drug (4.96%). The use of stimulants was much lower as compared to that in other reports and methylphenidate was the only one which was prescribed. The reports which showed an increased incidence of growth suppression with chronic stimulant use could be responsible for the lower prescription rates of these drugs in our study [23].

In Australia, one study shows 13 percent of all outpatients received more than one antipsychotic



medication [24]. In another study in India, 60 percent of in-patients received prescriptions for two or more antipsychotic medications [25]. In our study group, approximately 30% of the patients were receiving multiple antipsychotic medications.

Important findings were drug prescribed in generic form in higher percentage (91.73%) and majority of drugs (80.16%) supplied from hospital pharmacy. A good percentage of drugs are prescribed from NLEM 2011. The reason may be due to government policy of writing prescription compulsorily in generic name in West Bengal and free and adequate supply of medicine in government hospital pharmacy.

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In our study we did not look for the appropriateness of the psychotropic drugs which were prescribed for the various mental illnesses. Also, the rationality of the drug combinations was not assessed. Our study intended to present the drug utilization data in the child and adolescent attending the OPD of a government tertiary care hospital.

## CONCLUSION

To conclude, both in pediatric and adolescent age group male patients with psychiatric illness were more commonly presented to OPD than females. The most common diagnosis was behavioural and neurotic disorders, while the most commonly prescribed drugs were antidepressants and antipsychotics. Near about one third of the total sample received more than one psychotropic medication. A significant number of drugs are prescribed in generic name and distributed from hospital pharmacy at free of cost. Since all the drugs do not produce equal effects and to the same extent in children and adolescents, well controlled clinical trials are needed to establish their true benefit in this population. The long-term safety and quality of the life outcomes also need to be determined.

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