PRESCRIPTION PATTERNS OF BENZODIAZEPINES IN INDIAN ADULT POPULATION: A CROSS SECTIONAL STUDY

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ABSTRACT

Background: Benzodiazepines are the most common prescribed drugs in psychiatric practice with the main indications being anxiety, insomnia, panic attacks, mood disorders and substance withdrawal. There is a deficiency of data on prescription patterns of these drugs and presence of high abuse potential.

Aims and Objectives: This observational cross-sectional study was designed to study the prescription patterns of benzodiazepines in Indian adult population in psychiatry outpatient department of a tertiary general hospital.

Materials and Methods: In 1 year duration study, 400 patients on benzodiazepines enrolled in this study and they filled up a questionnaire designed for the study. The data was evaluated using descriptive statistics.

Results: A total of 225 (56.25%) patients were female and 175 (43.75%) were males. The mean age of the group was 41.34±12.61 years with a range of 19- 70 years. 75% patients were married and housewives (31.25%) were the patients prescribed with benzodiazepines. 52.50% patients were educated till primary school level. And The reasons for prescribing benzodiazepines were anxiety disorder in 96 (24%) patients followed by bipolar disorder in 63 (15.75%), followed by psychotic and mood disorders. Clonazepam and Lorazepam were the most commonly prescribed medications.

Conclusions: There is a requirement for data, which can help implement better strategy for regulation of the prescription of benzodiazepines at all levels. More studies will help articulate guidelines for prescribing this group of drugs for various indications rationally.

Keywords: Benzodiazepines, Clonazepam, Lorazepam, Prescription patterns

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INTRODUCTION

The first benzodiazepine Chlordiazepoxide discovered in 1955 and then the diazepam in 1963. Since then, several molecules have been obtained comprising a group of drugs having anxiolytic, hypnotic, anticonvulsant and muscle relaxant effects.[1] Benzodiazepines are essential medicines used for treatment of many clinical disorders, including anxiety, panic, phobias, depression, excitation, aggressiveness, insomnia, and epileptic attacks. They have fast onset of action, efficient, produce calming effect, promotes onset and maintenance of

sleep, and minimum acute toxicity are some of the advantages of using these medicines.[2] BZDs are categorized as Schedule IV drugs under the Controlled Substances Act in the US.[3] Studies have revealed prevalence of BDZs use up to 36% in developing countries.[4] A recent report presented benzodiazepine prevalence among adults age more than 65years is 8.6% in Unites states.[5] A prevalence of BZDs use evaluated was 9.2% from combined population of six European countries.[6] The prevalence of BZDs use in Canadian Province in elderly population surpasses 10%.[7]

The long-time benzodiazepine use by substantial part of the population and its adverse results such as somatic and cognitive side effects, interactions with other drugs and alcohol and its possible impairment of quality of life has incite a critical discussion about the tradition of prescribing benzodiazepines.[8] Age and gender have been a consistent factor in benzodiazepines as various studies have shown that, women represent the demographic characteristic most frequently associated with the use of benzodiazepines especially elderly female.[9,10,11]

BZDs act as positive allosteric modulators on the gamma amino butyric acid ($GABA_A$) receptor which is a ligand-gated chloride-selective ion channel. When BZDs bind to its site, they stimulate a conformational change in the $GABA_A$ receptor increasing chloride channel opening that hyperpolarizes the cell and cause inhibitory effect throughout the CNS.[12]

Benzodiazepine use leads to various adverse effects like increased accident risk, benzodiazepine use in the elderly include falls, cognitive impairment, sedation, and impairment of driving skills, all of which are mainly related to the long half-life of benzodiazepines and prolonged use should be opposed due to the risk of dependence.[13,14] The incidence of hip fracture seems to be associated with benzodiazepine use which is highest during the first 2 weeks after starting a benzodiazepine in elderly.[15]

The subsistence of Benzodiazepine dependence with very high dose of chlordiazepoxide has become a real concern for the medical community with increasing number of reports of withdrawal symptoms including dysphoria, irritability, sweating, unpleasant dreams, tremors, anorexia, and faintness or dizziness.[16] The study of prescribing pattern is a component of medical audit which seeks monitoring, evaluation and necessary modifications in the prescribing practices of the prescribers to achieve rational and cost effective medical care.[17]

A study reported that Sedatives and hypnotics were recurrently used for parasuicide (44%), followed by analgesics and antidepressants. Benzodiazepines and benzodiazepine-agonists were the most commonly used drugs (32%) for suicide among them.[18] Studies have also shown that the benzodiazepines were involved in suicide attempts, 80% which is also generalised to developing countries. It has been hypothesized that benzodiazepine administration leads to an increase in antagonistic and hostile tendencies. It adds to the economic burden making the medication expensive as per the patient's perspective and would indirectly result in non compliance. The objective of the present study was to estimate the frequency of benzodiazepine use among Indian adult population, and to conclude its associations with related socio-demographic and clinical characteristics which are unique to these populations.[19]

MATERIALS AND METHODS

This was a 1 year long cross-sectional study with sample size of 354 conducted in Department of Pharmacology, Government Medical College, Patiala in association with

Department of Psychiatry, Rajindra Hospital, Patiala which is a tertiary care, multi-speciality hospital attached to Government Medical College, Patiala. Patients who were eligible according to the inclusion and exclusion criteria were enrolled in the study.

INCLUSION CRITERIA

1. Adults of either gender.
2. Age > 18 years

EXCLUSION CRITERIA

1. Children, Pregnant women
2. Seriously and acutely ill patients
3. Patients having insufficient data records
4. Allergic patients

Data were collected from patients attending the psychiatry outpatient department on random sampling. The information was collected on a questionnaire containing questions based on patient sociodemographic data, diagnosis of psychiatric illness along with prescription of benzodiazepines given to the patient. The sociodemographic data included patient's OPD number, gender, age, marital status, occupation, education, and place of residence. Primary psychiatric diagnosis was noted, and benzodiazepine prescription information included questions about the indication, type, dosage, frequency, and route of administration and other concomitant medications and whether prescribed in generic name or not. The questions were answered by the patient themselves or their relatives and attendants. All patients had given informed consent from the patients or their attendants according to an approved protocol. The data were scrutinized using simple descriptive statistics. The study was approved by the Institutional Ethics Committee. This study analysed the prescription pattern by WHO core drug prescribing indicators including: (a) average number of drugs per encounter, (b) percentage of drugs prescribed by generic names, (c) percentage of antibiotics prescribed, (d) percentage of injections prescribed, and (e) percentage of drugs prescribed from the essential drugs list. National List of Essential Medicines (NLEM) 2022 of India was used for assessing the number of drugs prescribed from the essential list. Statistical analysis was done using IBM SPSS (Statistical Product and Service Solutions) version 22.0. Quantitative data was expressed using mean and standard deviation and qualitative data was expressed in frequency and percentage.

RESULTS

A total of 400 patients enrolled in 1 year duration of study. The mean age of the group was 41.34 ± 12.61 years with a range of 19-70 years (Table 1). 225 (56.25%) patients were female and 175(43.75%) were male (Table 2). 75% patients were married and 20.50% were unmarried and rest others were widow or divorced (Table 3). Housewife's (31.25%) were the most common patients prescribed with benzodiazepines followed by private job (19.75%) (Table 4). 210 (52.50%) were educated to primary school level and least (5%) were illiterate persons (Table 5).

Table 1: Distribution of Age in study population

Age (Years)	Patients	Percentage
18-27 Years	72	18%
28-37 Years	83	20.75%

38-47 Years	106	26.50%
48-57 Years	86	21.50%
58-67 Years	50	12.50%
≥68 Years	3	0.75%
Total	400	100%
Mean±SD	41.34±12.61	
Median	40.00	
Range	19-70	

Table 2: Distribution of Gender in study population

Gender	Patients	Percentage
Female	225	56.25%
Male	175	43.75%
Total	400	100%

Table 3: Distribution of Marital status in study population

Marital Status	Patients	Percentage
Unmarried	82	20.50%
Married	300	75%
Widow	14	3.50%
Divorced	4	1%
Total	400	100%

Table 4: Distribution of Occupation in study population

Occupation	Patients	Percentage
Unemployed	48	12%
Students	19	4.75%
Housewife	125	31.25%
Business	39	9.75%
Private Job	79	19.75%
Govt Job	13	3.25%
Farmer	37	9.25%
Labour	23	5.75%
Retired	17	4.25%
Total	400	100%

Table 5: Distribution of Education in study population

Education	Patients	Percentage
Illiterate	20	5%
Primary	210	52.50%
Matriculation	52	13%

Secondary	55	13.75%
Graduate	63	17.75%
Total	400	100%

Table 6: Distribution of Co-Morbidity in person with Mental Illness of study population

Co-Morbidity	Patients	Percentage
DM	25	6.25%
DM+CAD	1	0.25%
HTN	12	3%
HTN+DM	8	2%
Hypothyroid	10	2.50%
No Comorbidity	344	86%
Total	400	100%

The most common co-morbidity found in this study was diabetes mellitus in 25 (6.25%) patients followed by hypertension in 12 (3%) patients, hypothyroidism was seen in 10 (2.50%) patients (Table 6). The most common diagnosis in present study was generalised anxiety disorder in 96 (24%) patients followed by bipolar disorder in 63 (15.75%), followed by psychotic and mood (affective disorders) (Table 7). The most common benzodiazepine prescribed was Clonazepam in 240 (60%) patients followed by Lorazepam in 149 (37.25%), nitrazepam in 5 (1.25%), alprazolam and chlordiazepoxide in 3 (0.75%) patients respectively (Table 8). Most of the patients, 297 (74.25%) used benzodiazepines twice a day, 103 (25.75%) used once a day. In patient receiving clonazepam, commonly prescribed doses were 0.25 and 0.5 mg and 184(46%) were on twice a day dose and 56 (14%) were on once a day dosage. The strengths commonly prescribed were 0.25 and 0.5 mg. and in Lorazepam, 107 (26.75%) patients used twice a day dose and 42 (10.5%) patients used once a day dose and 2mg and 1mg were common prescribed dose. Other concomitant medications with benzodiazepines included antidepressants, selective serotonin reuptake inhibitors (SSRI), Escitalopram (10.28%) and Paroxetine (7.17%) (Table 9), and among atypical antipsychotics, Olanzapine (8.84%) and Risperidone (7.33%) were most commonly prescribed (Table 10). Divalproex (2.47%) was most common mood stabilizer (Table 11) and Trihexyphenidyl (6.85%) was anticholinergic prescribed in present study.

Table 7: Distribution of diagnosis as per ICD-10 in study population

Diagnosis as per ICD-10		Patients	Percentage
Schizophrenia, Schizotypal, Delusional and Other Non-Mood Psychotic Disorder	F20 (Schizophrenia)	50	12.50%
	F23 (Brief Psychotic Disorder)	10	2.50%
	F25 (Schizoaffective Disorder)	10	2.50%

	F28 (Other Psychotic Disorder)	16	4%
	F29 (Unspecified Psychosis)	16	4%
	Total	102	25.5%
Mood (Affective Disorders)	F31 (Bipolar Disorder)	63	15.75%
	F32 (Major Depressive Disorder, Single Episode)	39	9.75%
	F33 (Major Depressive Disorder, Recurrent)	22	5.50%
	Total	124	31%
Anxiety, Dissociative, Stress Related, Somatoform and Other Nonpsychotic Mental Disorder	F41 (Generalised Anxiety Disorder)	96	24%
	F42 (Obsessive Compulsive Disorder)	34	8.50%
	F43 (Reaction to Severe Stress and Adjustment Disorders)	42	10.50%
	F44 (Dissociative and Conversion Disorder)	2	0.50%
	Total	174	43.5%
	Total	400	100%

Table 8: Distribution of Benzodiazepines in study population

	Benzodiazepine with dose available	Dose given	Frequency	Route	Patients	Percentage
Short Acting	Midazolam (1mg/ml, 2mg/ml, 5mg/ml)	Nil	Nil	Nil	Nil	0%
	Triazolam	Nil	Nil	Nil	Nil	0%

	(0.125mg, 0.25mg)					
	Oxazepam (10mg, 15mg, 30mg)	Nil	Nil	Nil	Nil	0%
Intermediate Acting	Lorazepam (0.5mg, 1mg, 2mg)	2mg	BD	Oral	99	24.75%
		2mg	HS	Oral	34	8.5%
		1mg	BD	Oral	8	2%
		1mg	HS	Oral	8	2%
	Alprazolam (0.25mg, 0.5mg, 1mg, 2mg)	0.25 mg	BD	Oral	3	0.75%
	Nitrazepam (5mg, 10mg)	10 mg	HS	Oral	5	1.25%
	Estazolam (1mg, 2mg)	Nil	Nil	Nil	Nil	0%
	Temazepam (7.5mg, 15mg, 30mg)	Nil	Nil	Nil	Nil	0%
Long Acting	Clonazepam (0.125mg, 0.25mg, 0.5mg,1mg, 2mg)	0.5 mg	BD	Oral	177	44.25%
		0.5mg	HS	Oral	37	9.25%
		0.25 mg	BD	Oral	7	1.75%
		0.25 mg	HS	Oral	19	4.75%
	Chlordiazepoxide (5mg, 10mg, 25mg, 100mg)	10 mg	BD	Oral	3	0.75%
	Diazepam (2mg, 5mg, 10mg, 15mg)	Nil	Nil	Nil	Nil	0%
	Flurazepam (15mg, 30mg)	Nil	Nil	Nil	Nil	0%
Total					400	100%

Table 9: Distribution of Antidepressant Drugs in study population

Antidepressant Drugs		Frequency	Percentage
Selective Serotonin Reuptake	Fluoxetine	48	3.82%
	Fluvoxamine	20	1.59%
	Paroxetine	90	7.17%

Inhibitors (SSRI)	Sertraline	16	1.27%
	Escitalopram	129	10.28%
Tricyclic Antidepressants (TCA)	Amitriptyline	5	0.40%
	Dothiepin	6	0.48%
	Clomipramine	10	0.80%
	Melitracen	12	0.96%
Serotonin and Nor Adrenaline Reuptake Inhibitors (SNRI)	Desvenlafaxine	1	0.08%
	Duloxetine	2	0.16%
	Venlafaxine	9	0.72%
Atypical Antidepressants	Amoxapine	19	1.51%
	Mirtazapine	3	0.24%

Table 10: Distribution of Antipsychotic Drugs in study population

Antipsychotic Drugs			Frequency	Percentage
Atypical Antipsychotics		Risperidone	92	7.33%
		Olanzapine	111	8.84%
		Quetiapine	27	2.15%
		Clozapine	1	0.08%
		Aripiprazole	37	2.95%
		Amisulpride	29	2.31%
		Cariprazine	4	0.32%
		Lurasidone	0	0%
Typical Antipsychotics	Butyrophenone	Haloperidol	17	1.35%
	Thioxanthene	Flupentixol	12	0.96%

Table 11: Distribution of Mood Stabilizer Drugs in study population

Mood Stabilizers		Frequency	Percentage
Anti-Epileptic Drugs	Divalproex	31	2.47%
	Lamotrigine	23	1.83%
	Carbamazepine	8	0.64%
	Oxcarbazepine	2	0.16%
	Sodium Valproate	3	0.24%
Anti-Manic Drug	Lithium	19	1.51%

DISCUSISON

The prevalence of females in our study was higher than in males which is similar to study done by Simon GE et al and Ramdan WH et al where females were more than males.[20,21] And most of the patients are married and housewives which is similar to study done by Ahmer S et al. One possible explanation for increasing prevalence of benzodiazepine use among females may be the higher prevalence of anxiety and mood disorders in females.[22]

The psychological problems are more likely to be encountered by females as they live longer than men. Females can express their health problem much better than males, so their compliance towards prescribed medication is more.[23] Patients in our study were educated till primary school level which is similar to study done in India.[24] The most common co-morbidity found in this study was diabetes mellitus in 25 (6.25%) patients, hypertension in 12 (3%) patients and hypothyroidism was seen in 10 (2.50%) patients which is similar to study by Tripathi A et al in which diabetes was most common co morbidity.[25]

The most common diagnosis for prescription of benzodiazepines found in present study was generalised anxiety disorder which was seen in studies from abroad.[21,26,27] The most common benzodiazepine prescribed in present study was Clonazepam and Lorazepam which is similar to other studies.[24,28]

Table 12: WHO Prescribing Indicators

SR NO.	WHO PRESCRIBING INDICATORS	RESULTS
1.	Average number of drugs per prescription	3.14±0.95
2.	Percentage of prescriptions with an antibiotic prescribed	0%
3.	Percentage of prescriptions with an injection prescribed	0%
4.	Percentage of drugs prescribed by generic name	100%
5.	Percentage of drugs prescribed from an Essential Medicine List	63.59%

In present study, average number of drugs prescribed per prescription was 3.14±0.95 which is lower than other prescription pattern studies by Uddin MM et al in which the average number of drugs were 8.56±1.93 and Santos-Pérez MI et al in which mean drug consumption was 5.5±3.1. Average number of drugs per prescription is an important and have scope for review and educational intervention in prescribing practices. Prescription of higher number of drugs increases the risk of more drug interactions, decreased compliance of patients and increased cost. There is need to identify components of polypharmacy and create modifications in prescribing practices.[28.29] WHO prescribing indicators shown in Table 12.

Percentage of prescriptions with an antibiotic and an injection prescribed was 0% in present study. 100% drugs were prescribed by generic name. Percentage of drugs prescribed from National Essential Medicine List was 63.59%. In study conducted in Nigeria, 83% drugs were prescribed by generic names. This helps to decrease the cost of prescription as branded drugs are more expensive than the generic, which contain same active ingredients. 52% of the drugs were from the Nigeria's Essential Drugs List.[30] In a study by Tejus A et al 91.3% were by generic name, while 55.02% of prescriptions were from the essential drug list.[31] In study by Thakkar KB et al 76.01% of drugs were prescribed by generic name. In study by Greenblatt DJ et al drugs by generic name were 77% of all prescriptions, and 23% of prescriptions with brand name.[32,33]

By implementing policy tools including supply-side measures and demand-side measures, marketing of generic drugs can be increased.[28] It reflects physician's knowledge of pharmacology and pathophysiology and expertise in diagnosis and attitude towards selecting the most appropriate cost effective treatment.[34] There is a desperate need to

analyzed the prescription pattern of benzodiazepines to regulate their usage. It is worth mentioning that most of the studies on benzodiazepine are done in developed nations where prescriptions are well regulated.[24] Moreover, present study gives an understanding for conducting similar studies in future about prescription patterns by covering multicentric population and adding more parameters to provide feedback to clinicians and to encourage rational prescription.

CONCLUSION

More studies are needed to be done regarding prescription of benzodiazepines, that would help to articulate guidelines for prescribing this group of drugs for various indications rationally. Many studies have reported the decrease in the benzodiazepine prescription by efficient approach. All these matters can only be solved in the presence of considerable and credible data, which can navigate the policies to regulate the prescription of benzodiazepines at all levels and their effectual implementation.

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