RESEARCH PAPER

A Study on Drug Utilization Evaluation of Benzodiazepines and Its Complications in a Tertiary Care Hospital, Tamilnadu

Dr. V.S. Shriramu[1*], Dr. Farhana Rahman[2], Dr. Arul Amutha Elizabeth[3]

[1*] Postgraduate, Department of Pharmacology, Sree Balaji Medical College and Research Institute, BIHER, Chennai, Tamil Nadu, India. (Corresponding Author)

[2] Professor, Department of Pharmacology, Sree Balaji Medical College and Research Institute, BIHER, Chennai, Tamil Nadu, India.

[3] Professor & H.O.D, Department of Pharmacology, Sree Balaji Medical College and Research Institute, BIHER, Chennai, Tamil Nadu, India.

Corresponding Author: Dr. V.S. Shriramu, Postgraduate, Department of Pharmacology, Sree Balaji Medical College and Research Institute, BIHER, Chennai, Tamil Nadu, India.

Email: dr.shriramu@gmail.com | Phone no: 9894331418

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ABSTRACT

Background: Benzodiazepines (BZD) have become one of the most commonly prescribed classes of drugs due to their multiple therapeutic actions such as anxiolytics, sedatives, seizures, muscle relaxants and dependence syndrome. Epidemiologic data from Europe, Canada, Japan and Australia indicate that rates of benzodiazepine use in the general population were found to be around 6%. It is reported that BZDs are often prescribed without any appropriate documentation for its use in the patients. The aim of this study is to assess the rationale use of benzodiazepines and its complications among various departments in a Tertiary care hospital.

Methods: A prospective study was conducted with a sample size of 200 for a period of three months. Data was collected from patients based on inclusion and exclusion criteria. Naranjo Adverse Drug Reaction Probability Scale and Drug Interaction Probability Scale (DIPS) were used as a study tool to measure the causality of adverse drug reactions and drug interactions. Based on the dosage of various benzodiazepines, Defined Daily Dose (DDD) was calculated and compared with WHO Anatomical Therapeutic Chemical (ATC) classification.

Results: BZD's were mostly prescribed in males (74.5%) and married patients (86.5%) were more exposed to benzodiazepines compared to others. Lorazepam (70.1%) was found to be the most commonly used drug, mainly prescribed for sedation, followed by anxiety. DDD was calculated and majority of patients had DDD in accordance with WHO standard. Based on cost analysis, Clobazam was found to be the high cost and Lorazepam being the low-cost drug. The results of drug utilization evaluation of benzodiazepines study along with its complications were compiled and reported to the respected department physician and their feedback was collected.

Conclusion: The study envisages the Rational use of Benzodiazepines. Also it showed that the negative outcomes of BZD can be reduced by providing drug-related information to the prescribers and consumers.

Keywords: Benzodiazepines, Drug utilization, Naranjo adverse drug reaction scale, Drug Interaction Probability Scale (DIPS), Defined Daily Dose (DDD).

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INTRODUCTION

Drug utilisation studies are employed as a potential tool in the evaluation of the health care system, and key concerns with drug usage patterns, prescribing practice, and gaps between guidelines have been addressed. Benzodiazepines have long been used to treat different

psychiatric diseases, sleeplessness, acute alcohol withdrawal, and epilepsy [1]. Such studies help in optimizing the rational use of drugs in a clinical setting [2].

DUE denotes the prescription of a well-documented drug in an appropriate dose for the correct indication, with accurate information, and at a reasonable price. It also gives information about pharmacological efficacy, or whether a specific drug therapy is cost effective.

Benzodiazepines (BZD) have become one of the most often prescribed drug groups because to their numerous therapeutic activities, which include anxiolytics, sedatives, seizures, muscle relaxants, and dependency syndrome [3].

According to epidemiologic data from Europe, Canada, Japan, and Australia, the general population's rate of benzodiazepine use was determined to be approximately 6%. BZDs are frequently administered without proper documentation for their use in patients [3].

Psychiatric patients regularly take medications off-label; clonazepam and lorazepam have been found to be the most commonly used medications off-label [4].

One key factor for the present overuse of benzodiazepines is a dearth of particular information about the detrimental effects of benzodiazepines as well as alternatives such as non-benzodiazepine sedatives [5]. BZDs have been linked to a variety of deleterious effects, both long-term and short-term, as well as a higher prevalence of drug-drug interactions in mental patients [5, 6].

Benzodiazepines were associated with improved patient quality of life when used for a short period of time and in lower doses [7]. The present study aimed to assess the rationale of BZD usage by evaluating the prescription pattern and drug-related problems among various departments in a Tertiary care hospital, Chennai.

MATERIALS AND METHODS

The research was carried out at the Sree Balaji Medical College and Research Institute in Chennai, Tamil Nadu. This study was approved by the Institution Human Ethics Committee (IHEC, SBMCH) of the hospital. Patients or carers who refused to give informed consent were excluded from the study. A prospective study of Drug Utilisation Evaluation of Benzodiazepines was undertaken to examine the prescription pattern, drug-related problems, indication, and dose of the medications, as well as assess the drug usage pattern utilising DDD. The study was conducted for a period of 6 months. The study includes departments such as general medicine, cardiology, gastroenterology, psychiatry, neurology, and orthopaedics. Patients aged 18 to 65 who had been administered any formulation of benzodiazepines and were able to communicate were considered eligible for the study, whereas paediatrics and outpatients were excluded. Patients were approached in the respected departments based on the inclusion and exclusion criteria. Prior to data collection, patients were asked to sign a consent form after being informed about the study in a regional language. Data regarding the socio-demographic and clinical characteristics of the patients were obtained through interviews and past medical records. From the drug chart review, current drugs, together with dosage, frequency, method of administration, and duration of therapy, have been noted and examined for drug interactions, adverse drug reactions, contraindications, and the cost of benzodiazepine therapy during the hospital stay. Follow up of patients will be continued till the patient is on BZD therapy during hospitalization or till discharge.

$$\text{DDD} = \frac{\text{Number of items issued} \times \text{Amount of drug per item (mg)}}{\text{WHO recommended DDD of drug}}$$

RESULTS

The study was conducted among 200 patients based on the inclusion and exclusion criteria.

Table 1 provides the baseline characteristics. Out of 200 patients, the gender breakdown reveals that 74.5% were men and 25.5% were women. According to social habits, 25% of people were alcoholics, 7.5% were smokers, and 15.5% were both. 86.5% of patients who received benzodiazepine prescriptions were married. When compared to unemployed patients, working individuals were prescribed benzodiazepines at a higher rate (56.5%).

Table 1: Baseline characteristics

Characteristics		No of patients (n)	Percentage (%)	P value
Gender	Male	149	74.5	0.001
	Female	51	25.5	
Social habits	Smoker	15	7.5	0.03
	Alcoholic	50	25	
	Both	31	15.5	
	None	104	52	
Marital status	Single	25	12.5	0.80
	Married	173	86.5	
	Others	2	1	

Employment	Employed	113	56.5	0.032
	Unemployed	87	43.5	

Table 2 depicts the pattern of benzodiazepine use, with lorazepam prescribed for 70.1% of cases. The cardiology department was found to have the highest benzodiazepine consumption rate (44.5%) out of the six departments. Sedation accounted for 40.3% of the clinical conditions treated with benzodiazepines, with anxiety coming in second with 36.3% of patients. A substantial majority of patients (81.6%) did not experience any adverse drug reactions (ADRs), while 18.4% did. The majority of patients, or 81.6%, had no drug interactions.

Table 2: Pattern of benzodiazepines usage

Characteristics		**Lorazepam (n=141)**	**Diazepam (n=1)**	**Clonazepam (n=25)**	**Alprazolam (n=12)**	**Clobazam (n=10)**	**Chlordiazepoxide (n=12)**	**Total**	**P value**
Departments, n(%)	**Cardio**	87(43.2)	0	0	1(0.5)	0	1(0.5)	89(44.5)	**0.000**
	Ortho	0	0	0	2(1)	0	0	2(1)	
	Gen. Med	8(4)	0	1(0.5)	0	0	3(1.5)	12(5.5)	
	Psych	31(15.3)	1(0.5)	17(8.5)	1(0.5)	2(1)	5(2.5)	57(28.5)	
	Neuro	6(3)	0	3(1.5)	3(1.5)	8(4)	3(1.5)	23(11.5)	
	Gastro	9(4.5)	0	4(2)	5(2.5)	0	0	18(9)	
Clinical condition, n(%)	**Sedation**	65(32.3)	0	9(4.5)	3(1.5)	2(1)	2(1)	81(40.3)	**0.000**
	Anxiety	44(21.9)	1(0.5)	11(5.5)	9(4.5)	4(2)	4(2)	73(36.3)	
	Insomnia due to anxiety	22(10.9)	0	1(0.5)	0	0	0	23(11.4)	
	Seizure	0	0	4(2)	0	4(2)	0	8(4)	
	ADS	10(5)	0	0	0	0	6(3)	16(8)	
Drug related problems of BZDs: ADR, n(%)	**Definite**	0	0	0	0	0	0	0	**0.000**
	Probable	2(1)	1(0.5)	0	0	2(1)	1(0.5)	6(3)	
	Possible	25(12.4)	0	2(1)	1(0.5)	1(0.5)	1(0.5)	30(15)	
	Doubtful	0	0	1(0.5)	0	0	0	1(0.4)	
	Nil	114(56.7)	0	22(11)	11(5.4)	7(3.5)	10(5)	164(81.6)	
Drug Interactions, n(%)	**Highly probable**	0	0	0	0	0	0	0	**0.001**
	Probable	6(3)	0	0	0	1(0.5)	0	7(3.5)	

	Possible	13(6.5)	0	6(3)	5(2.5)	4(2)	1(0.5)	29(14.4)	
	Doubtful	0	0	0	0	1(0.5)	0	1(0.5)	
	Nil	122(60.7)	1(0.5)	19(9.5)	7(3.5)	4(2)	11(5.5)	164(81.6)	

Table 3 displays the mean and median benzodiazepine specified daily doses. In our study, the average DDD of patients using lorazepam 2 mg was 2.6, which exceeded the recommended DDD of 2.5. Similarly, the mean DDD of diazepam 10 mg surpassed 30 times the standard (10). Benzodiazepines were prescribed to 90 patients in accordance with the WHO ATC criteria.

Table 3: Mean and median of benzodiazepines defined daily dose

Drugs	**Dose (mg)**	**n(%)**	**WHO ATC DDD (mg)**	**Mean DDD (mg) (DDD)**	**Median DDD (mg) (DDD)**
Lorazepam	1	47(52.3)	2.5	1.4(0.57)	1(0.4)
	2	19(21.2)	2.5	2.6(1.045)	2(0.8)
Diazepam	10	1(1.1)	10	30(3)	30(3)
Clonazepam	0.5	5(5.5)	8	0.46(0.06)	0.48(0.06)
	1	1(1.1)	8	2(0.25)	2(0.25)
Alprazolam	0.25	2(2.2)	1	0.25(0.25)	0.25(0.25)
	0.5	7(7.8)	1	0.52(0.52)	0.5(0.5)
Clobazam	5	1(1.1)	20	5(0.25)	5(0.25)
	10	3(3.3)	20	18.5(0.92)	18(0.89)
Chlordiaze-poxide	10	2(2.2)	30	20(0.67)	20(0.67)
	20	2(2.2)	30	20(0.67)	20(0.67)

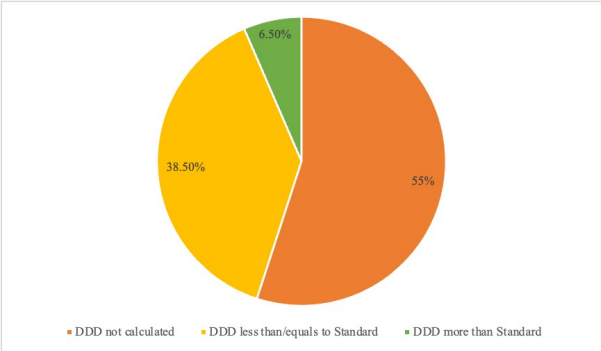
Table 4 shows the patient division into two groups based on the BZD prescription: below 5 days and above 5 days. The mean dose of various generic BZDs was calculated and compared between patients with and without ADR in each group. A positive correlation (p= 0.017) was observed with Lorazepam taking patients less than 5 days and a negative correlation with patients taking chlordiazepoxide and clobazam for more than 5 days and clonazepam less than 5 days.

Table 4: Comparison of ADRs based on mean dose of various generics of BZDs

Drug	**5 DAYS**					**Above 5 DAYS**				
	n(%)	**ADR at dose (mg)**	**n(%)**	**No ADR at dose (mg)**	**P value**	**n(%)**	**ADR at dose (mg)**	**n(%)**	**No ADR at dose (mg)**	**P value**
Lorazepam	19(9.5)	5.1	75(37.3)	4.97	0.017	8(4)	15.125	39(19.4)	11.897	0.130
Clonazepam	0	0	7(3.4)	58.57	-	2(1)	60	3(1.5)	173.33	-0.688
Alprazolam	2(1)	1.5	16(8)	2.19	-0.266	1(0.5)	14	6(3)	4.42	0.946
Clobazam	0	0	6(3)	1.5	-	1(0.5)	5	5(2.4)	3.15	0.389
Chlordiaze-poxide	2(1)	40	3(1.5)	21.67	0.809	1(0.5)	80	4(2)	272.5	-0.570

Figure 1 demonstrates the appropriateness of benzodiazepines based on defined daily doses: 55% had DDD greater than the standard, 38.5% had DDD less than or equal to the standard, and DDD was not computed for 6.5% of patients.

Fig. 1: Appropriateness of BZD's based on DDD



DISCUSSION

A study on drug utilisation evaluation of benzodiazepines and its complications was undertaken in a tertiary care hospital to examine the rational use of benzodiazepines in 200 patients. According to our study, the percentage of BZD was higher in alcoholics, and men are prescribed benzodiazepines at a significantly higher rate than females (p= 0.001) [9]. These findings were consistent with earlier research, but women used benzodiazepines at a higher rate than men [15].

Since married people are known to experience greater mental strain than single persons, we found that the married group received higher BZD prescriptions in our study [7]. The prescription of BZDs was shown to be higher in cardio patients than in psychiatry, as cardio patients are more prone to be nervous and restless about their condition, demonstrating the scientific reason for BZD use in people with heart disease. Because of its short-acting action, which also enhances patients' emotional state and quality of life, lorazepam is the BZD that is most frequently administered to patients.

In contrast to a 2016 study that found that BZDs were largely used for anxiety (44.4%), the current analysis demonstrates that BZDs were mostly utilised for sedation, followed by anxiety conditions[10,16]. Since the cardiology department included the majority of the study's patients, sleeplessness may be a risk factor for the development of excessive blood pressure, congestive heart failure, and heart failure [11]. Overall, 64.1% of patients were prescribed 4 to 6 days of BZDs, and the BZD prescription increases with the length of the hospital stay.

According to Table 2, 18.4% of patients had ADRs like fatigue and vertigo. Similar to the earlier study, ADRs were commonly observed in patients taking lorazepam and resulted in the direct extension of CNS depressive qualities [12, 13]. Clinical pharmacists intervened in 11% of cases, discontinuing the medicine in 8% and reducing the dose in 3%.

According to the analysis of drug interactions, Lorazepam exhibited a higher rate of drug interactions in 18.5% of patients, which is consistent with the findings of the previous study [14]. During our study period, only one patient out of 200 was admitted with BZD dependent syndrome and treated with long acting BZD (Diazepam).

DDD per patient is calculated in patients who are prescribed BZDs for their primary indications as anxiolytics and anti-epileptics. Using the WHO ATC DDD as a standard reference, it was shown that, as shown in fig. 1, 38.5% of patients received prescriptions in accordance with it, whereas 6.5% of patients used it inappropriately (above the standard DDD).

Table-3 shows that the DDD of patients using Lorazepam 2 mg (2.6 mg) surpassed the usual DDD (2.5 mg), which can be avoided by reducing the dose. It was found that the mean and median of DDD/patient were 2. and 5.64. A patient was exposed to 5.64 DDDs throughout the course of an average 6-day hospital stay, which is determined to be reasonable.

Based on the study, 31.3% of patients kept using benzodiazepines after being discharged. An analysis of drug-related issues after discharge revealed that 6% of patients experienced drug-drug interactions and 5.47% had developed ADRs during their hospital stay.

Table-4 demonstrates that patients with lorazepam prescriptions for fewer than 5 days showed a significant (p=0.017) positive connection, while patients with prescriptions for more than 5 days showed an insignificant result for Clonazepam, Alprazolam, and lorazepam. This illustrates that ADRs rely on dosage in patients using Lorazepam, regardless of how long their prescription for BZD lasts.

According to our research, Clobazam is the most expensive BZD when compared to other options. However, when considering the duration of therapy, it was discovered that chlordiazepoxide contributed 45% and Lorazepam, a low-cost medicine, contributed 70.1% to the whole BZD prescription, showing reasonable drug use.

Based on feedback from the physicians, Lorazepam was the most preferred medication, followed by Alprazolam

and Clonazepam. Benzodiazepines were used long-term for alcohol withdrawal and seizures, and short-term for anxiety and insomnia. With the exception of cardiology, where 61.7% of BZD prescriptions were issued, 5 out of 6 doctors advised mental state exams before writing BZD prescriptions. This may be done to prevent BZD overuse. The fact that not all benzodiazepines had a defined daily dose was a study constraint.

CONCLUSION

Lorazepam was discovered to be the most generally prescribed medicine because to its beneficial activity when compared to other benzodiazepines, and its use was found to be more prevalent among cardiac patients in the short term. Significantly more dose-dependent adverse drug reactions were found in patients using Lorazepam. To confirm that dose-dependent adverse drug reactions (ADRs) cause additional BZDs, more research is needed. By using a more suitable dosage and transitioning to non-BZD sedatives at the time of discharge, drug-related issues can be minimised. The WHO ATC/DDD values are limited in what can be considered as a reference value because they are based on international data. A safe, effective and optimum therapy can be provided to the patient by minimizing the negative outcomes and thereby ensuring the rationale in its use.

CONFLICT OF INTERESTS: None

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