



## Research Article

### **PRESCRIPTION PATTERNS OF SEDATIVE DRUGS, EFFICACY AND DAYTIME SEDATION IN VARIOUS PSYCHIATRIC PATIENTS IN A TEACHING HOSPITAL**

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Article Received on: 05/08/18 Approved for publication: 14/09/18

**DOI: 10.7897/2230-8407.099211**

#### **ABSTRACT**

**Objectives:** To study the prescription patterns of sedative drugs, efficacy and daytime sedation in various psychiatric patients in a tertiary care hospital - Sri Venkateswara Institute of Medical Sciences (SVIMS), Tirupati, Andhra Pradesh, India. **Materials and methods:** A retrospective cross-sectional study was carried out for 6 months, patients of all ages and both sexes were included in the study. **Results:** The diagnostic pattern mainly divided by neurosis (68%) and psychosis (32%). The prescription pattern was divided into monotherapy (45 %) and polytherapy (55 %). Neurosis (68%) was more prevalent than psychosis in respect to patients with sedative drugs. Patients Clonazepam 65 % was the most commonly prescribed drug among all the classes of drugs. In the sleep efficacy study, 79 %, 18 %, 3 %, patients had good, fair and poor sleep respectively. Using Epworth Sleepiness Scale scoring, 43%, 3%, 16%, 7% has normal daytime sedation, mild, moderate & severe daytime sedation respectively. Unpaired t-test was performed between mono and polytherapy of total sleep efficacy showed that (0.6) there was no significance. Mann Whitney U test was performed for Epworth Sleepiness Score between mono and polytherapy patients (0.9) showed that there was no significance in daytime sedation between the patients on both mono and poly therapies. **Conclusion:** In future, a larger survey may be conducted to covering the aspects such as providing counseling and reduce the less sleep efficiency in patients, and finding out pharmacokinetics of the drugs to prescribe the correct doses of drugs to the patients.

**Keywords:** Retrospective study, Neurosis, Psychosis, Epworth Sleepiness Scale

#### **INTRODUCTION**

Annually 1,500 mortalities and 71,000 personal injuries are a result of sleep problems attributed to 1, 00,000 motor vehicle accidents. An estimated 20% of the population has excessive daytime sleepiness which is the most common sleep-related patient symptom. The utmost accepted cause of excessive daytime sleepiness includes sleep deprivation, obstructive sleep apnea, and sedating medications.<sup>1</sup> The important reason for excessive daytime sleepiness (EDS) for chronic schizophrenia includes drug-induced sleepiness after an anti psychotic sedative action.<sup>2</sup> The initial sign of psychiatric problems or symptomatic psychiatric disorders may be insomnia.<sup>3</sup> The familiar side effect of typical neuroleptic therapy is sedation, eminently when taken at high doses. Few atypical antipsychotic medications can also cause sedation. Neither all conventional anti-psychotics nor all atypical antipsychotics have the same sedative effect.<sup>4</sup>

The pharmacological agents that act on the central nervous system are most commonly reported to have sleepiness as a side effect. For screening of the patients with excessive daytime sleepiness, authenticated questionnaires such as the Stanford Sleepiness Scale and Epworth Sleepiness Scale are used. Patients with excessive daytime sleepiness can be assessed by using questionnaire and providing them with scores.<sup>5</sup> although psychotropic drugs have had a remarkable impact in psychiatry, their utilization in actual clinical practice, effectiveness, and

safety in the real-life situation needs continuous study.<sup>6</sup> As there is no sufficient data available on their use in the population of central India, the present study was carried out to analyze the pattern of psychotropic drug utilization in the psychiatric out-patient department (OPD), Sri Venkateswara Institute of Medical Sciences (SVIMS), Tirupati, Andhra Pradesh, India.

#### **MATERIALS AND METHOD**

##### **Study design and ethical consideration**

We conducted the retrospective cross-sectional study on the prescription patterns of sedative drug's efficacy and daytime sedation in various psychiatric patients in a tertiary teaching hospital Sri Venkateswara institute of Medical Sciences, Tirupati, Andhra Pradesh, India. The ethical clearance was obtained from the Institutional Ethical Committee and the number was IEC NO. 617, were received from the same study site and the consent has taken from subjects and study was in accordance with ICH GCP Guidelines.

##### **Selection criteria**

##### **Inclusion criteria**

1. Patients of both the gender aged above 18 years.
2. Patients who were willing to participate.

3. Patients who visit the outpatient department after  $\geq 1$  month of constant sedative drug use
4. Patients who are adherent to the therapy

**Exclusion criteria**

1. Patients who are not willing to participate
2. Patients below 18 years of age
3. Female patients who are pregnant.
4. Patients who are non-adherent
5. Patients who had a head injury
6. Patients suffering from mental illness and substance dependence.

**Sample size**

One hundred hospital outpatients who are treated with antipsychotic drugs for various psychiatric disorder prescription were analyzed as per the study need.

**Method of collection of data**

1. Written informed consent was obtained from all subjects participating in the study
2. Patient Demographic Data form was obtained from all patients participating in the study
3. Data was collected from both the patient and patient case profile. Data regarding the prescription patterns were collected from the patient case profile, wherein data pertaining sleep efficiency and data time sedation was collected from the patient through sleep efficacy scale and Epworth Sleepiness Scale.<sup>7</sup>

**Study procedure**

In the Psychiatric Department, all the patients were reviewed daily to identify the patients prescribed with sedative drugs. Patients were divided into the different groups according to their age. A total of 100 prescriptions of sedative drugs were collected from patient medical records. Prescriptions were collected irrespective of the indications. Patients demographic details such as name, age, sex, clinical data such as diagnosis, therapeutic data other concomitant medications, duration of therapy and other necessary details were collected by scrutinizing patient's medical records medication charts and Questionnaire form. The collected information was documented in a suitably designed data collection form. Patient's prescriptions were screened for any possible drug interactions and ADRs that had occurred with Antipsychotic Drugs.

**Statistical analysis**

The data collected was recorded in a pre-designed proforma and managed using Microsoft Excel worksheet (Microsoft Corp, Redmond, WA) and SPSS (Statistical Package for Social Sciences). After obtaining the data, sleep efficacy and daytime sleepiness was determined using total sleep efficacy scale and Epworth Sleepiness Scale respectively. The ESS score and sleep efficacy score was compared between Monotherapy and polytherapy using unpaired T-test and Mann Whitney U test respectively. A 2 tailed P- value  $< 0.05$  is considered statistically significant. Mann Whitney U test was considered as the standard deviation was greater than half of mean in total sleep efficacy; unpaired T-test was considered as the standard deviation was less than half of mean in Epworth sleepiness scoring.

**Table 1: Age group and diagnostic pattern of the sample in the department of psychiatry**

| S.No | Age   | Psychiatric illness           |                              |
|------|-------|-------------------------------|------------------------------|
|      |       | No of patients with Psychosis | No of patients with Neurosis |
| 1    | 18-27 | 8                             | 10                           |
| 2    | 28-37 | 7                             | 15                           |
| 3    | 38-47 | 10                            | 25                           |
| 4    | 48-57 | 5                             | 9                            |
| 5    | 58-67 | 2                             | 5                            |
| 6    | 68-77 | 0                             | 3                            |
| 7    | 78-87 | 0                             | 1                            |

**Table 2: Age groups in monotherapy and polytherapy in the department of psychiatry**

| S.No | Age group | Monotherapy (n=45) | %  | Polytherapy (n=55) | %  |
|------|-----------|--------------------|----|--------------------|----|
| 1    | 18-27     | 9                  | 20 | 9                  | 16 |
| 2    | 28-37     | 8                  | 18 | 14                 | 25 |
| 3    | 38-47     | 16                 | 35 | 19                 | 34 |
| 4    | 48-57     | 5                  | 11 | 9                  | 16 |
| 5    | 58-67     | 3                  | 6  | 4                  | 7  |
| 6    | 68-77     | 3                  | 6  | 0                  | 0  |
| 7    | 78 above  | 1                  | 2  | 0                  | 0  |

**Table 3: Prescribed sedative drugs as polytherapy for psychiatric illness in the department of psychiatry**

| S.No                         | Polytherapy                     | Neurosis | Psychosis | Total |
|------------------------------|---------------------------------|----------|-----------|-------|
| <b>Two drug combinations</b> |                                 |          |           |       |
| 1                            | Chlordiazepoxide+ Amitriptyline | 1        | 0         | 1     |
| 2                            | Lorazepam+ Risperidone          | 0        | 1         | 1     |
| 3                            | Alprazolam+ Clonazepam          | 1        | 0         | 1     |
| 4                            | Clonazepam+ Amitriptyline       | 1        | 0         | 1     |
| 5                            | Clonazepam+ Desvenlafaxine      | 3        | 0         | 3     |
| 6                            | Clonazepam+ Mirtazapine         | 1        | 0         | 1     |
| 7                            | Clonazepam+ Clozapine           | 1        | 1         | 2     |
| 8                            | Clonazepam+ Quetiapine          | 1        | 1         | 2     |
| 9                            | Clonazepam+ Olanzapine          | 1        | 2         | 3     |
| 10                           | Clonazepam+ Risperidone         | 1        | 1         | 2     |

|                                |  |   |   |   |
|--------------------------------|--|---|---|---|
| 11                             | Amitriptyline+ Olanzapine  | 0 | 1 | 1 |
| 12                             | Venlafaxine+ Mirtazapine   | 1 | 0 | 1 |
| 13                             | Desvenlafaxine+ Quetiapine   | 0 | 1 | 1 |
| 14                             | Desvenlafaxine+ Olanzapine   | 2 | 0 | 2 |
| 15                             | Quetiapine+ Risperidone  | 0 | 2 | 2 |
| 16                             | Olanzapine+ Risperidone  | 0 | 3 | 3 |
| 17                             | Risperidone + Valproate  | 0 | 2 | 2 |
| 18                             | Quetiapine + Valproate   | 0 | 2 | 2 |
| 19                             | Olanzapine + Valproate   | 0 | 2 | 2 |
| <b>Three drug combinations</b> |  |   |   |   |
| 20                             | Chlordiazepoxide+ Clonazepam+Amitriptyline                         | 3 | 0 | 3 |
| 21                             | Lorazepam+ Olanzapine+Risperidone                                  | 1 | 0 | 1 |
| 22                             | Clonazepam+ Desvenlafaxine+Olanzapine                              | 3 | 0 | 3 |
| 23                             | Clonazepam+ Amitriptyline+Olanzapine                               | 1 | 0 | 1 |
| 24                             | Clonazepam+ Mirtazapine+Quetiapine                                 | 1 | 0 | 1 |
| 25                             | Clonazepam+ Olanzapine+Risperidone                                 | 0 | 1 | 1 |
| 26                             | Clonazepam+ Nortriptyline+ gabapentin                              | 0 | 3 | 3 |
| 27                             | Nortriptyline + Desvenlafaxine + gabapentin                        | 0 | 1 | 1 |
| 28                             | Quetiapine + Olanzapine+Risperidone                                | 0 | 1 | 1 |
| 29                             | Alprazolam+Clonazepam+Valproate                                    | 1 | 0 | 1 |
| <b>Four drug combinations</b>  |  |   |   |   |
| 30                             | Chlordiazepoxide+ Amitriptyline+ Nortriptyline + gabapentin        | 1 | 0 | 1 |
| 31                             | Chlordiazepoxide+ Clonazepam+ Amitriptyline + Desvenlafaxine       | 1 | 0 | 1 |
| 32                             | Alprazolam+ Clonazepam+ Nortriptyline + Gabapentin                 | 1 | 0 | 1 |
| 33                             | Clonazepam + Nortriptyline + Desvenlafaxine+ Gabapentin            | 2 | 0 | 2 |
| 34                             | Clonazepam+ Nortriptyline + Olanzapine+Gabapentin                  | 1 | 0 | 1 |
| <b>Five drug combinations</b>  |  |   |   |   |
| 35                             | Clonazepam+ Nortriptyline + Olanzapine+ Gabapentin+ Desvenlafaxine | 1 | 1 | 1 |

Table 4a: Doses of prescribed sedative drugs as monotherapy in the department of psychiatry

| S.No | Drug        | Minimum dose Prescribed in mg/ day | Maximum dose Prescribed in mg/ day | Mean dose (SD) in mg/ day |
|------|-------------|------------------------------------|------------------------------------|---------------------------|
| 1    | Clonazepam  | 0.25                               | 1                                  | 0.5786                    |
| 2    | Olanzapine  | 5                                  | 10                                 | 7.74                      |
| 3    | Risperidone | 3                                  | 4                                  | 3.6                       |

Table 4b: Doses of prescribed sedative drugs as polytherapy in the department of psychiatry

| S.No | Drug             | Minimum dose Prescribed in mg/ day | Maximum dose Prescribed in mg/ day | Mean dose (SD) in mg/ day |
|------|------------------|------------------------------------|------------------------------------|---------------------------|
| 1    | Chlordiazepoxide | 5                                  | 10                                 | 9.167                     |
| 2    | Lorazepam        | 1                                  | 1                                  | 1                         |
| 3    | Alprazolam       | 0.25                               | 0.25                               | 0.25                      |
| 4    | Clonazepam       | 0.25                               | 1                                  | 0.5151                    |
| 5    | Amitriptyline    | 10                                 | 25                                 | 20.27                     |
| 6    | Nortriptyline    | 10                                 | 10                                 | 10                        |
| 7    | Venlafaxine      | 75                                 | 75                                 | 75                        |
| 8    | Desvenlafaxine   | 50                                 | 100                                | 60.714                    |
| 9    | Mirtazapine      | 15                                 | 30                                 | 25                        |
| 10   | Clozapine        | 300                                | 300                                | 300                       |
| 11   | Quetiapine       | 50                                 | 200                                | 88.89                     |
| 12   | Olanzapine       | 5                                  | 10                                 | 8.05                      |
| 13   | Risperidone      | 1                                  | 4                                  | 2.66                      |
| 14   | Gabapentin       | 100                                | 400                                | 130                       |
| 15   | Valproate        | 500                                | 1500                               | 875                       |

SD- Standard deviation

Table 5: Sedative drugs induced sleep efficiency in the study population

| S.No | Sleep efficiency    | Male | Female | Neurosis | Psychosis | Total |
|------|---------------------|------|--------|----------|-----------|-------|
| 1    | 60-70 (Poor sleep)  | 1    | 2      | 3        | 0         | 3     |
| 2    | 70-90 (Fair sleep)  | 9    | 9      | 10       | 8         | 18    |
| 3    | 90-100 (Good sleep) | 31   | 48     | 55       | 24        | 79    |

Table 6: Comparisons of sleep efficiency score and Epworth sleepiness scale among the study population

| S.No | Sleep groups        | Epworth sleepiness scale |             |                  |                | Total |
|------|---------------------|--------------------------|-------------|------------------|----------------|-------|
|      |                     | Normal (0-7)             | Mild (8-11) | Moderate (12-15) | Severe (16-24) |       |
| 1    | 60-70 (Poor sleep)  | 2                        | 0           | 0                | 1              | 3     |
| 2    | 70-90 (Fair sleep)  | 9                        | 6           | 3                | 0              | 18    |
| 3    | 90-100 (Good sleep) | 32                       | 25          | 13               | 9              | 79    |

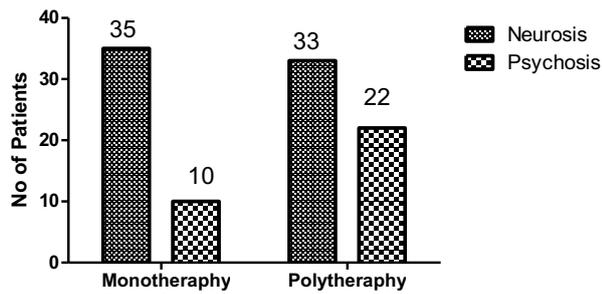


Fig. 1. Prescription patterns of sedative drugs in psychiatric illness in the department of psychiatry

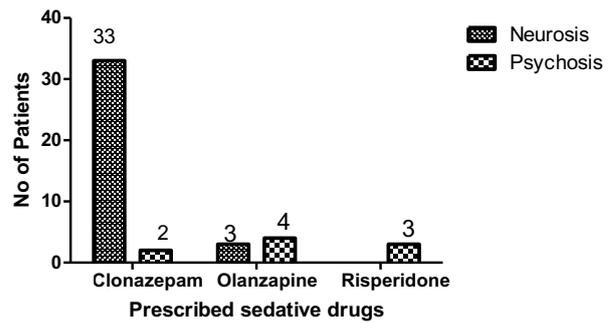


Fig. 2. Prescribed sedative drugs as monotherapy for psychiatric illness in the department of psychiatry

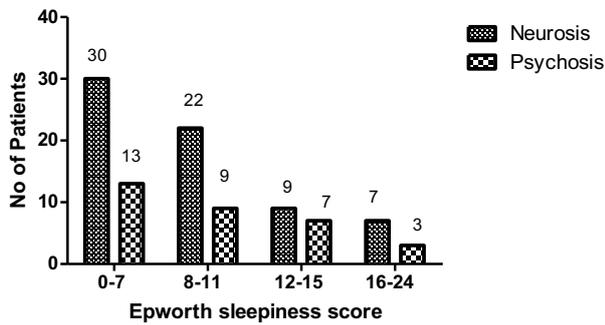


Fig. 3: Total sleep efficiency and Epworth sleepiness scale scoring in diagnostic patterns in the study population

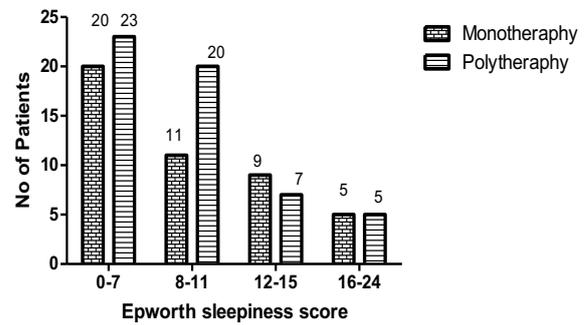


Fig.4: Epworth sleepiness scale scoring in monotherapy and polytherapy in the study population

**RESULTS**

**Socio-demographic data of the sample**

Out of 100 patients treated with Antipsychotic drugs, male subjects were 41% (41) and the female subjects were 59% (59) which indicates that females were mostly prescribed with a sedative drug compared to male. Out of all the patients included in the study 85% were married and the rest 15% were unmarried. Out 59 female patients 54 were married and 5 were unmarried; out of 42 male patients 31 were married and 10 are unmarried.

The study includes patients ≤ 18years of age of which patients under age group 18 - 27years were 18%, 28 -37 years were 22%, 38 -47 years were 35%, 48 -57 years were 14% 58 - 67 years were 7%, 68 -77 years were 3 %, 78 -87 years was 1 %.

**Diagnostic distribution**

The diagnostic pattern has been mainly categorized into 2 types: one is neurosis and other psychosis. A total number of patients diagnosed with neurosis was 68 and 32 with psychosis shown in table 1. Which indicates that more patients who are on sedative drugs are neurotic than psychotic as has been seen in another study.<sup>8</sup>

**Prescription pattern of the study sample**

The patients were divided into monotherapy and polytherapy based on their prescription patterns. Overall patients with monotherapy were 45 and 55 were polytherapy which indicates that polytherapy is most prevalent than Monotherapy in patients receiving sedative drugs as shown in fig 1. (Patients on monotherapy in neurosis – 35 and in psychosis – 10 & patients on

polytherapy in neurosis – 33 and in psychosis – 22). Monotherapy and polytherapy in different age groups of the subject population also shown in table 2.

**Monotherapy**

In patients on monotherapy, drugs prescribed were Clonazepam in total 35 patients with the dose of 0.25mg in 5 patients, 0.50mg in 16 patients, 0.75mg in 8 patients & 1mg in 4 patients among neurotic patients and 0.50mg in 2 psychotic patients; Olanzapine was prescribed in 7 patients with the dose of 5mg in 3 neurotic patients, the dose of 5mg and 10mg in 1 and 3 psychotic patients respectively; Risperidone was prescribed in 3 patients with the dose of 3mg & 4mg in 1 and 2 psychotic patients. Most of the patients on monotherapy was on clonazepam, followed by Olanzapine and risperidone were shown in Fig. 2.

**Polytherapy**

Inpatient on polytherapy, the two-drug combination prescribed were in total 33 (patients in neurosis 14 and psychosis 19) the three-drug combination prescribed were in 15 (patients in neurosis 10 and psychosis 5) the four-drug combination prescribed were in 6 (patients in neurosis 6 and psychosis were none) the five drug combination prescribed were in 1 patients (the one were in neurosis and psychosis were none) which is shown in table 3. Details of the mean dose along with most commonly prescribed sedative drugs in mono and polytherapy showed in table 4a. and 4b respectively.

### Sedative drugs induced sleep efficiency in a sample population

Sleep potency is that the magnitude relation of the overall time spent asleep (total sleep time) during a night compared to the entire amount of time spent in bed. If an individual spends a majority of the time that they're within the bed really asleep, then they're thought-about to sleep efficient (or to possess a high sleep efficiency). However, if an individual spends a plenty of the overall time that they're in bed awake, then that's not thought-about to sleep efficient (or the person has low sleep efficiency). In the present study, broadly divided the sedative drugs induced sleep efficiency of the patients based on the score into 3 types such as good sleep (90-100) fair sleep (70-90) and poor sleep (60-70) shown in table 5.

Epworth sleepiness scale measures a person's general level of daytime sleepiness or their average sleep propensity in daily life. Interpretation of Epworth sleepiness scale is based on the score. If the score is <8, it represents normal daytime sleepiness, 8 to 11 represents Mild sleepiness, 12 to 15 represents Moderate sleepiness and 16 to 24 represents severe sleepiness.

Based on prescription patterns, Epworth sleepiness scale measurement on monotherapy and polytherapy treated study population shown in Fig 4. finally, the comparison of sleep efficiency score and Epworth sleepiness scale among the study population in the tertiary care teaching hospital SVIMS, It's shown in the table 6.

Unpaired t-test was performed between monotherapy and polytherapy of total sleep efficacy showed that (the result was 0.6) there was no significance in total sleep between the patients on both monotherapy and polytherapy representing the drug efficacy was same in patients on both mono and poly therapies. Mann Whitney U test was performed for Epworth Sleepiness Score between monotherapy and polytherapy patients (the result was 0.9) showed that there was no significance in daytime sedation between the patients on both mono and poly therapies.

### DISCUSSION

In the current study, we assessed the prescription patterns, efficacy, and daytime sedation of psychotropic drugs through a retrospective cross-sectional study. Out of 250 Patients assessed, 100 psychiatric out-patients were included in the study that satisfied the inclusion and exclusion criteria. More female patients visited the psychiatry OPD than men. Many studies have reported a similar finding.<sup>9-11</sup> the reproductive age group (20-40 years) accounted for the majority of all the psychiatric disorders, as has been seen in many other studies.<sup>12-15</sup>

The most prescribed medication comes under the category Benzodiazepines in which Clonazepam (65) and Chlordiazepoxide (6) were the most commonly indicated followed by Alprazolam (02) and Lorazepam (02). Which is contradictory to earlier report such that alprazolam was the most commonly prescribed benzodiazepine followed by lorazepam.<sup>16</sup> Among Antidepressants, the most commonly prescribed drugs were Desvenlafaxine (12) & Mirtazapine (12) followed by Amitriptyline (9) & Nortriptyline (9). Among Antipsychotics, the most commonly prescribed drugs include Olanzapine (25) and Risperidone (15). Among Anticonvulsants, the most prescribed drug was valproate (10) and Gabapentin (9).

Based on the prescription patterns, patients were divided into monotherapy and polytherapy. Patients with monotherapy were given Clonazepam (35), Olanzapine (7) and Risperidone (3)

individually. In polytherapy: among 2 drugs combinations: Olanzapine+Risperidone (3), Clonazepam+Desvenlafaxine(3), clonazepam+Olanzapine(3) were the most commonly prescribed combination drugs, among 3 drugs combination: Clonazepam + NT + Gabapentin(3), Chlordiazepoxide + Clonazepam + Amitriptyline (3), among 4 drugs combination : Clonazepam + Nortriptyline + Desvenlafaxine + Gabapentin (2) and among 5 drugs combination : Clonazepam + Nortriptyline +Olanzapine+ Desvenlafaxine+Gabapentin (1) was the most commonly prescribed drug combination. Since no prescription had more than five drugs; we can say that polypharmacy was avoided. Polypharmacy can lead to poor compliance, drug interactions, adverse drug reactions, under-use of effective treatments and medication errors.<sup>17-18</sup>

Certain important findings emerge from this study. This study shows that most of the females [59 out of 100] were prescribed with sedative drugs; Neurosis [68 out of 100] was more prevalent than psychosis in respect to patients with sedative drugs; Polytherapy [55 out of 45] exceeded than Monotherapy; patients under the age group 38-47 years [35 out of 100] were most prescribed with sedative drug with mean age being; clonazepam [65 out of 100] was the most commonly prescribed drug among all the classes of drugs.

In the sleep efficacy study, 79 patients had good sleep, 18 patients had fair sleep and 3 patients had poor sleep. Among 3 patients with poor sleep efficacy, 2 patients were on clonazepam monotherapy and one patient was on polytherapy with drugs Alprazolam, Clonazepam and Valproate. But these findings are not sufficient to conclude that clonazepam may not cause proper sedative action because all the other patients prescribed on Clonazepam (62) had either fair or good sleep efficacy and they need further intervention. Using Epworth Sleepiness Scale scoring, 43 patients had normal daytime sedation, 31 had mild, 16 had moderate & 7 patients had severe daytime sedation. Among the patients with severe daytime sedation 4 patients were on clonazepam, 4 on Olanzapine, 2 on desvenlafaxine and mirtazapine and/or monotherapy or polytherapy which could be concluded that clonazepam and Olanzapine may cause severe daytime sedation and necessary intervention should be made in certain patients.

### CONCLUSION

Even though the current study observed the prescription pattern and identified the critical areas focused in addressing the daytime sedation, it does not reflect the true prescription patterns on a large volume of patients due to the limited patient flow. In future, a larger survey may be conducted covering many important aspects such as providing counseling to the patients to improve their sleep in patients with less sleep efficiency and finding out pharmacokinetics of the drugs to prescribe the correct doses of drugs to the patients; apart from prescription patterns, sleep efficacy, daytime sedation and thereby providing intervention which would be appropriate to the patient.

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**Cite this article as:**

Sivanandh Budarapu et al. Prescription patterns of sedative drugs, efficacy and daytime sedation in various psychiatric patients in a teaching hospital. Int. Res. J. Pharm. 2018;9(9):187-192 <http://dx.doi.org/10.7897/2230-8407.099211>

Source of support: Nil, Conflict of interest: None Declared

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