Prospective study of prescription patterns in outpatients of psychiatry department in a teaching hospital in Gulbarga

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Abstract
Introduction: Mental disorders form an important public health priority. Less work has been carried out in India on the economic burden of mental illness. Policy makers are increasingly dependent on clinical data to formulate and implement guidelines on Psychotropic drug use. This study aims to further the database of knowledge regarding Psychotropic drugs and their utilisation in mental health disorders in this region.
Materials and Methods: After institutional ethics committee approval, a prospective drug utilisation study of 100 out patient prescriptions was undertaken. Preparation of the protocol and conduct of the study was as per the WHO – DUS and the STROBE guidelines.
Results: 100 prescriptions were analysed containing 207 drugs, 174 of these were psychotropic drugs. Utilisation from National Medicines List and WHO Essential Medicines List was 54.54% and 45.45% respectively. Average psychotropic drugs per prescription were 1.74 ± 0.066 (SD). 30% prescriptions contained fixed dose combinations. Only 0.48% drugs were prescribed by generic name. Drug utilisation pattern: Commonly prescribed drugs were Haloperidol, Valproate, Dosulepin, and Clonazepam. The PDD/DDD ratio of three drugs – Risperidone, Lorazepam and Amisulpride – was equal to one. The average cost borne by the patient was 385.2 rupees per month.
Conclusion: Overall the principles of rational prescribing were followed. Hospital schedule needs to add more SSRIs. Practice of using typical anti–psychotics as first line was as per recommendations. More drugs need to be prescribed by generic name to reduce the economic burden. Use of drugs from essential medicine lists needs to be increased in order to have more rational prescribing.

Keywords: Drug utilization, Defined daily dose, Prescribed daily dose, Prescription pattern, Psychotropic drugs.

Introduction
The WHO defined drug utilisation research in 1977 as "The marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic implications".[1] Evidence provided by pre marketing clinical trials drives therapeutic practice, but complementary data from the post-marketing period are needed to improve drug therapy.[2]

Mental disorders form an important public health priority, both in terms of population suffering from mental disorders and from perspective of social and economic burden of these disorders. Epidemiological studies report prevalence rates for psychiatric disorders from 9.5 to 370/1000 populations in India.[3] Out of the top ten conditions contributing to the disability adjusted life years (DALYs), four are mental disorders.[4] The past 5 decades have seen notable advances in drug discovery and development for treating depression and anxiety.[5]

One of the reports that appeared in The Lancet stated how the recent global financial crisis shone a light on the mental health issues in India.[6] Although research on actual cost in treating widely prevalent diseases has appeared in medical literature, less work has been carried out in India on the economic burden of mental illness.

Drug cost per se accounts for a substantial part of health expenditure. Providing quality care with limited financial resources is the general focus of health programmes.[1] Hence, policy–makers are dependent on clinical data to formulate and implement optimum guidelines for use of Psychotropic drugs. Psychotropic drug utilisation studies can be useful in monitoring treatment for mental disorders on a population level.

Thus, drug utilisation studies of psychotropic drugs have crucial role in the final aim of attainment of mental health. Keeping this in mind we conducted our study with the following objectives:

1. To study the prescribing pattern of psychotropic drugs amongst psychiatrists at Basaveshwar Teaching and General Hospital, Gulbarga, Karnataka.
2. To assess the rationality of the prescriptions.
3. Analysis of cost benefit ratio.

Materials and Methods
1. Study design: It is a prospective cross-sectional drug utilisation study.
2. Ethical consideration: The Study was conducted after obtaining permission from the Institutional Ethics Committee (IEC) and the Psychiatry Department. All the data collected, as a part of this study was kept strictly confidential and used for the purpose of this study only.
3. Selection criteria: All patients who attended the Psychiatry outpatient department of Basaveshwar Teaching and General Hospital, Gulbarga from July 2013 to August 2014 with a diagnosed mental illness and at least one psychotropic drug prescribed.
4. Sample size: A total of 100 prescriptions were analysed. Sampling was based on convenience since it was first study of its type in the region. One random patient was selected on two days each week for 15 months.

5. Study procedure: The data was collected directly from the patients leaving the OPD and was recorded in a structured case record form.
6. Data analysis:

The following data was collected: Demographic data of patients, prescriber information, diagnosis, prescription details like date, number of drugs, names of individual drugs (generic/brand), any Fixed Dose Combination (FDC) prescribed, whether the prescribed drug(s) was available from the hospital pharmacy or to be bought by the patient from a private chemist, dose, dosage form, dosing schedule, duration of treatment and next follow-up date.

Drug cost was obtained from the Hospital Drug Store and/or various drug indexes: the Drug Index – April – June 2014.[7] Psychotropic drugs in the hospital drug schedule were listed out. Prescription pattern assessment[8] was done as per WHO INRUD (International network of rational use of drugs) guidelines. Descriptive statistics were used to determine the extent and patterns of psychotropic drug use in the Psychiatry OPD.

Pattern of psychotropic drug use as per DUS metrics[1]: The prescribed drugs were classified according to The ATC (Anatomical Therapeutic Chemical) classification and DDD (Defined Daily Dose), PDD (Prescribed Daily Dose) and PDD/DDD ratios were calculated.

Cost of drugs prescribed from the hospital schedule was calculated using the rate contract available in hospital drug store. Cost of drugs bought from pharmacies outside the hospital, was obtained from the Drug Index April-June 2014.[7] A descriptive statistical analysis was carried out. The results on the continuous measurement scale were presented as Mean ± SD (Min-Max) and the results on the categorical measurement type were presented as a number (%).

Results

Out of a total of 100 participants, the percentage of female and male patients was equal (50% each). The age range was 17 to 65 years with the average age being 32.85 years. The age and gender distribution is shown in Table 1. 24% percent of prescriptions analysed were of patients diagnosed with schizophrenia, 33% with mood disorders and 37% with anxiety disorders. The remaining prescriptions were categorised as 'other psychiatric illnesses'. The relative distribution of the various disorders was as shown in Fig. 1.

Analysis of prescription patterns: (Table 2).

Multiple WHO INRUD drug use indicators were utilised in this analysis. 100 prescriptions were analysed containing a total of 207 drugs. Out of these 174 were psychotropics. None of the prescriptions contained more than 4 drugs. The number of drugs prescribed from the hospital drug schedule was 105 and all of the drugs were available in the hospital pharmacy. Fixed dose combinations of psychotropic drugs prescribed were Risperidone 3 mg + Trihexiphenidyl 2 mg prescribed to 16 patients and Paroxetine 12.5 mg + Clonazepam 0.5 mg prescribed to 4 patients. Haloperidol, Olanzapine, Fluoxetine, Lithium, Sodium Valproate, Escitalopram accounted for 50.72% of all drugs prescribed from hospital drug schedule. The percentage utilisation from the Nation and WHO essential drug list was 54.4% and 45.5% respectively.

Drugs used in various psychiatric disorders were as follows:

1. Schizophrenia and other psychoses: (n = 24): Fig. 2
2. Mood disorders: (n=33): Fig. 3
3. Anxiety disorders: (n=37): Fig. 4

Pattern of psychotropic drug use as per anatomic therapeutic classification/defined daily dose (ATC/DDD) is shown in table DDDs mentioned in the table are for oral route (obtained from the WHO ATC/DDD website).[9] Formula used for conversion of dose of lithium from mg to mmol was: mg/l × 0.144 = mmol/l × 6.94

PDD/DDD ratio of psychotropic drugs prescribed are presented in Fig. 5

Cost analysis of Prescriptions

The average cost per prescription was Rs. 384.23/month, 89.3% of which was due to psychotropic drugs.

Discussion

Study Participants

In our study male and female participants were of equal number (50 each). However studies have questioned the prevailing pattern of mental disorders in both genders and have reported that psychiatric disorders are more common in females.[10-12] The reproductive age group (20-40yrs) (Table 6) accounted for the majority, i.e., almost half of all the psychiatric disorders. This finding was consistent with many studies.[13-15] Anxiety disorder was the most common diagnosis followed by schizophrenia, depression and bipolar mood disorders, in that order (Fig. 1). Piparva et al. found that schizophrenia was the most common diagnosis in Gujarat in 2010 unlike in our study where anxiety disorders came first. It was followed by depression whereas, in our study schizophrenia came in second.[13]

Analysis of prescriptions as per the WHO/INRUD drug use indicators: (Table 2)

The average number of psychotropic drugs per prescription was 1.74, which was lower than that found in similar such studies, where it ranged from 2.3 to 3 drugs per prescription.[13-17] No prescription contained more than four drug. Thus, polypharmacy was seemingly avoided while prescribing drugs in this psychiatry OPD. Current guidelines recommend implementing monotherapy as first line for most of the psychiatric disorders and only if necessary, adding other drugs if there is evidence of clear benefit while taking into consideration any possible drug interactions.[18] A very low proportion of drugs (0.48%) were prescribed by their generic names. This was probably because in our setup the drugs are dispensed in the pharmacy at retail and available under brand names since this is a corporate setup. In our study no injections were prescribed to any of the participants during the course of the study. Many Indian trials have evaluated the efficacy of depot antipsychotics in schizophrenia and have found them useful in the

management of acute phases of schizophrenia and also for maintenance.[19] Two fixed dose combinations (FDCs) were found to be prescribed: trihexiphenidyl hydrochloride 2 mg plus risperidone 3 mg prescribed to 16 patients, paroxetine 12.5 mg plus clonazepam 0.5 mg prescribed to 4 patients. The first combination is easily available and often prescribed in schizophrenia and other psychoses. It might indicate an increase risk of over prescription of the anticholinergic drug trihexiphenidyl. Though in our study a very low percentage of prescriptions contained this combination (16%). Notably, most of the antipsychotic drugs themselves have mild anticholinergic effects. Many researches have warned that the addition of anticholinergic medication can exacerbate existing tardive dyskinesia (TD), and that discontinuing anticholinergic drugs may improve the condition. The observation has led to the hypothesis that these compounds might also contribute to the development of TD.[20,21] WHO does not recommend routine use of anticholinergics for preventing extrapyramidal side-effects in individuals with psychotic disorders treated with antipsychotics but recommends their use for short term in selected cases. Overall, FDCs have their own advantages and disadvantages, which need to be taken into consideration on a patient-to-patient basis.

Observed prescription pattern in Schizophrenia: (Fig. 2)

In our study, conventional /1st generation anti psychotic: haloperidol (50%) and the atypical anti psychotic risperidone (25%) were most commonly prescribed. The 1st generation anti psychotics were being prescribed widely as per the current recommendations and more so because they were available in the hospital drug store. It was previously believed that the newer/2nd generation drugs were more effective, but that belief no longer holds good. Also, the guidelines of the National Institute of Clinical Excellence (NICE, 2010), suggest that it is not necessary to prescribe an "atypical" agent as first line treatment.[22] No benzodiazepines were prescribed to our study participants diagnosed with schizophrenia and other psychoses. Guidelines for the rational use of benzodiazepines recommend their use for short term (maximum, four weeks) or intermittent courses in minimum effective doses, to be prescribed only when symptoms are severe.[23]

Observed prescription pattern in Mood disorders: (Fig. 3)

Among the antidepressants, dosulepin (21%) was most commonly prescribed followed by escitalopram (24.5%) and lorazepam (18%). Overall, SSRIs were prescribed more than TCAs. This is in concordance with the current recommendations (APA and NICE) and practice in the management of mood disorders.[24,25] SSRIs have a better adverse-effect profile compared to other anti depressants and are hence preferred. Even in cardiac disorders these are relatively unproblematic except citalopram, which is associated with dose-dependent QT prolongation.[26,27] According to the 2008 American College of Physicians guideline[28], all these agents have similar efficacy and choice among different second-generation antidepressants should be based on adverse effects, cost, and patient preferences. Patient's response to therapy, and adverse effects of antidepressants should be assessed within 1-2 weeks of starting therapy.

Among the drugs used in bipolar mood disorders, valproate was most commonly prescribed (39.39%). Lithium was used only in 6 patients of bipolar disorder. The second-generation antipsychotic risperidone was used in 30% patients. Studies have shown that extremes of mania and depression can be managed with mood-stabilising drugs and they can reduce the number of episodes of mania and depression. Kessing et al. found lithium to be more superior to valproate in general.[29] However, because of the low therapeutic index for Lithium (Li^+), periodic determination of serum concentrations is essential and Li^+ cannot be used with adequate safety in patients who cannot be regularly tested.[30] The concern regarding its narrow therapeutic index and difficulty in monitoring drug levels of lithium could explain the low use of lithium observed in our study. Many drug utilisation studies have reported similarly low use of lithium in bipolar disorders.[31,32]

Observed prescription pattern in Anxiety disorders: (Fig. 4)

Clonazepam was the most commonly prescribed drug (48.6%) for anxiety disorders, followed by the SSRI escitalopram (35.1%), the beta-blocker propranolol (29.7%), lorazepam (21.6%), fluoxetine (18.9%), paroxetine and clomipramine (13.9% each). The 2011 NICE guidelines for the management of anxiety disorders states that SSRIs or Serotonin Norepinephrine Reuptake inhibitors (SNRIs) should be the first choice offered to the patient. Benzodiazepines should generally be avoided and used only in the short term in case of crisis.[33] Benzodiazepines act quickly but carry the liability of physiological and psychological dependence. They can be used as adjunct in initial stage of therapy with SSRIs and tapered off over 4-12 weeks.[34] Alprazolam was not prescribed to any patient in our study.

ATC/DDD Classification and DUS metrics: (Table 3)

In our study, risperidone, lorazepam and amisulpride had PDD/DDD ratios equal to 1. Most of the drugs had the PDD/DDD ratios below 1 and the drugs haloperidol, escitalopram, sertraline, fluoxetine (highest PDD/DDD ratio) had their ratios above 1.

Drugs with PDD/DDD ratio lesser or greater than 1 are either under or over utilised. Often PDD can vary due to factors like illness treated, national therapeutic procedures, etc. For example PDDs are often lower in Asian than in Caucasian populations. It does not mean there is under utilisation of the drug. Also WHO ATC/DDD data gives DDD for management of moderate intensity hence the WHO encourages countries to have their own DDD list based on local data.[1]

Cost Analysis

The average cost per prescription was 385.2 rupees per month. All of the drugs were available and dispensed from the hospital drug store. We do not have any previous studies to compare this parameter with. It is important to keep in mind that total healthcare cost is a combination of expenditure on travel, and the time and money spent in consulting. In a developing country like India, cost is an important factor that determines compliance.[35] This is especially important in psychiatric disorders, where the duration of treatment is long and level of compliance can vary from as much as 20 to 50% because of various factors.[36]

Limitations of our Study

There exist some limitations to our study. Since we selected patients visiting the psychiatric OPD, the observed prevalence of various psychiatric disorders and their distribution may not be generalisable to the population at large due to Berkson's bias. The physicians were aware that the prescriptions were being analysed and that could have led to a modicum of bias too. As with any cross sectional drug utilisation study, it was not possible to monitor the actual use or compliance of the patients with the prescribed drugs. Hence the consumed daily dose (CDD) could not be calculated. We could not compare the clinical effectiveness and adverse effect profile of various psychotropic drugs prescribed since we considered the information purely from the prescriptions of the patients without referring to the actual case records themselves.The choice of drugs depends on the severity of the disease, which we were not able to consider; as such data was not available from the prescriptions. During the calculation of the cost borne by the patient we couldn't take into consideration any financial assistance the patient might have got from various sources, thereby further lowering the patient's economic burden. Ours was an exploratory study and hence we have kept the sample size to minimum.

At the same time, our study also has numerous strengths. Ours was a one of its kind study done in this region regarding utilisation of drugs in psychiatry out patient department. It was one of the very few indigenous studies that have analysed the drug utilisation pattern of psychotropic drugs comprehensively and compared it with the recent guidelines. We have used the various drug utilisation metrics like ATC/DDD classification, PDD, PDD/DDD ratios, and cost parameters to present our data in a scientific manner so as to enable comparisons with other such studies.

Table 1: Gender and age distribution observed in a sample of prescriptions of patients (n=100) attending the psychiatry out patient department

Characteristic		Number of patients
Gender	Male	50
	Female	50
Total		
Age	<20	6
	20-40	75
	41-60	17
	>60	2
Total		100

Table 2: Assessment of the prescription patterns as per the various drug use indicators, in a sample of patients (n=100) attending the psychiatry out patient department

S. No.	Drug use indicator	Result
1.	Average number of drugs per prescription: Mean ± SD	2.07±0.68
2.	Average number of psychotropic drugs per prescription: Mean ± SD	1.74±0.66
3.	Percentage of prescriptions containing FDCs	30%
4.	Percentage of drugs prescribed by generic name	0.48%
5.	Percentage of prescriptions with an injection prescribed	0.00%
6.	Percentage of psychotropic drugs prescribed from hospital drug schedule	50.72%
7.	Percentage of psychotropic drugs actually dispensed from the hospital drug store	100%

Table 3: ATC/DDD classification, PDD values and PDD/DDD ratio of psychotropic drugs prescribed to a sample of patients (n=100) attending the psychiatry outpatient department

S. No.	Drug	ATC code	DDD* (mg)	PDD (mg)	PDD/ DDD
1	Aripiprazole	N05AX12	15	10	0.66
2	Valproic acid	N03AG01	1500	600	0.40
3	Haloperidol	N05AD01	8	10	1.25
4	Clozapine	N05AH02	300	100	0.33

5	Risperidone	N05AX08	5	5	1.00
6	Dosulepin	N06AA16	150	89.3	0.59
7	Olanzapine	N05AH03	10	3	0.30
8	Escitalopram	N06AB10	10	20	2.00
9	Lorazepam	N05BA06	2.5	2.5	1.00
10	Lithium	N05AN0	24 (mmol)**	12.44	0.51
11	Sertraline	N06AB06	50	100	2.00
12	Fluoxetine	N06AB03	20	46.66	2.33
13	Clonazepam	N03AE01	8	0.5	0.06
14	Amisulpride	N05AL05	400	400	1.00
15	Trihexiphenidyl	N04AA01	10	4	0.40
16	Venlafaxine	N06AX16	100	75	0.75
17	Paroxetine	N06AB05	20	13.88	0.69
18	Clomipramine	N06AA04	100	75	0.75

*DDDs mentioned in the table are for the oral route as obtained from the WHO ATC/DDD website 2012.
** For conversion of dose of lithium from mg to mmol the formula used was: mg/l × 0.144 = mmol/l × 6.94
ATC code – Anatomical Therapeutic Chemical Classification code, DDD – Daily defined dose, PDD – Prescribed daily dose.

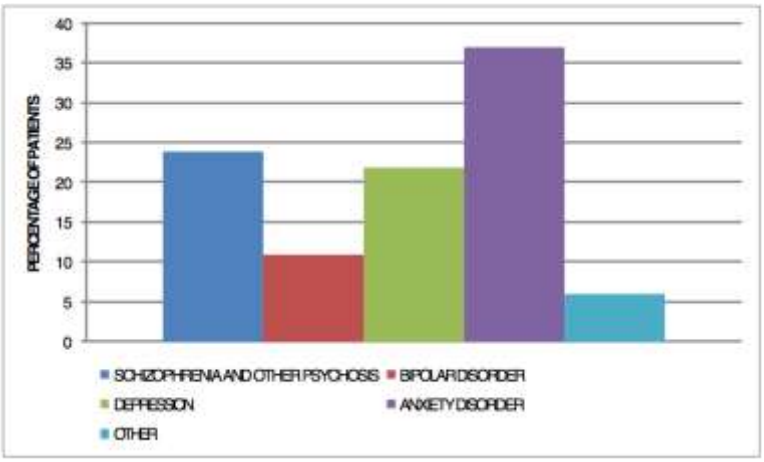

Fig. 1: Pattern of psychiatric disorders observed in a sample of prescriptions of patients (n=100) attending the psychiatry out patient department

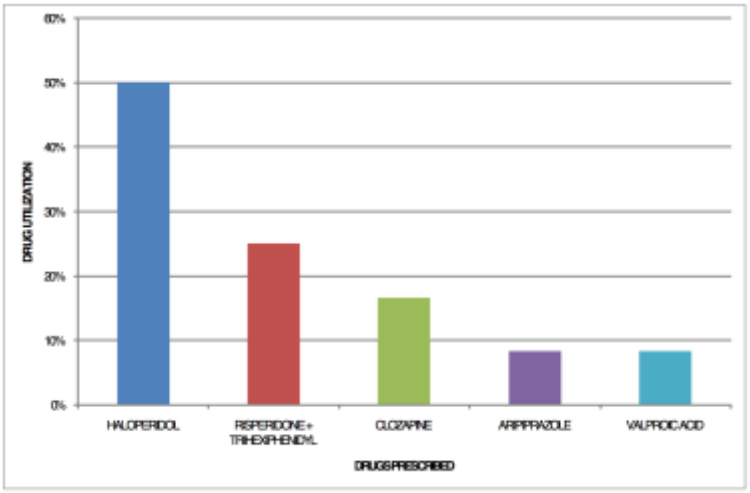

Fig. 2: Percent utilisation of drugs in a sample of prescriptions of patients (n=24) suffering from schizophrenia and other psychoses attending the psychiatry outpatient department

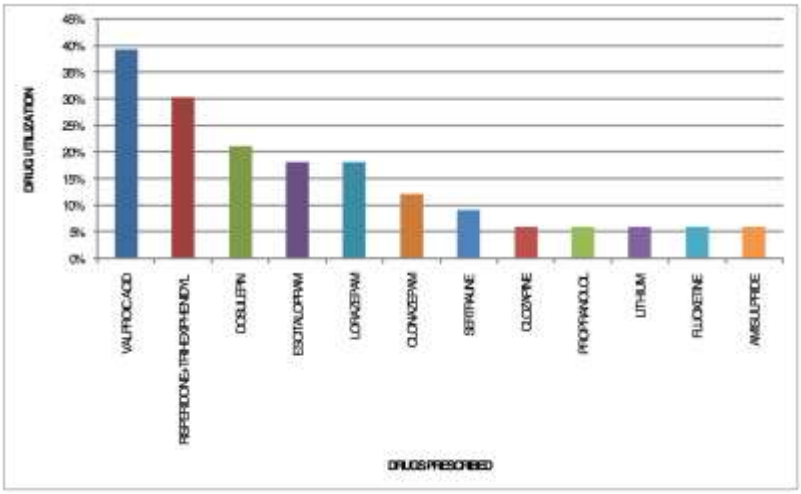

Fig. 3: Percent utilization of drugs in a sample of prescriptions of patients (n=33) suffering from various mood disorders (depression and bipolar disorder) attending the psychiatry outpatient department

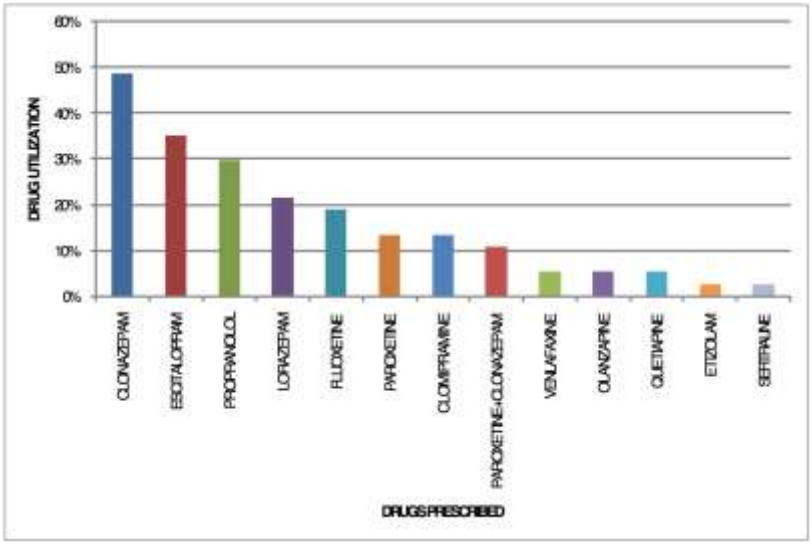

Fig. 4: Percent utilization of drugs in a sample of prescriptions of patients (n=37) suffering from anxiety disorders attending the psychiatry outpatient department

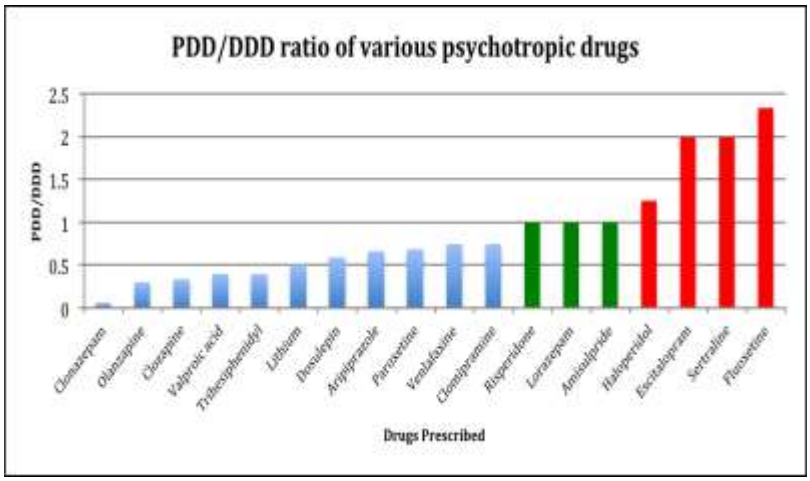

Fig. 5: PDD/DDD ratio of psychotropic drugs prescribed to a sample of patients (n=100) attending the psychiatry outpatient department

Conclusions

In our study anxiety disorder was the most common diagnosis followed by schizophrenia, depression and bipolar disorder. In Schizophrenia and other psychotic conditions the most commonly prescribed single drug and fixed dose combination were, haloperidol and risperidone + trihexiphenidyl, respectively. In Bipolar disorders, the most commonly prescribed drug was valproate and the least commonly prescribed drug was amisulpride. In Depression, the most commonly prescribed drug was dosulepin and the least commonly prescribed drug was fluoxetine. In Anxiety disorders, the most commonly prescribed drug was clonazepam and the least commonly prescribed drug was sertraline.

Overall, the principles of rational prescribing were followed according to the various drug use indicators mentioned by WHO/INRUD. A few deviations were found from the guidelines (APA and NICE) due to socioeconomic reasons, budgetary constraints and technical difficulties.

The following recommendations can be made based on our study, to improve the pharmacotherapy of various psychiatric disorders and hence the overall outcomes:

1. The Hospital Drug Schedule: Need to add drugs like SSRIs, so that they can be prescribed more frequently as first line agents.
2. Drugs need to be prescribed by generic name so that the economic burden on the patients can be reduced.
3. The use of drugs from the National and WHO essential medicine list needs to be increased in order to have more rational drug prescribing.
4. The practice of using 1st generation/typical antipsychotics as first line should be continued.
5. Depot formulations of antipsychotics can be tried in selected cases to improve treatment outcomes.
6. Anticholinergics should be used only in selected cases of patients on anti-psychotics.
7. Lithium can be used in a greater proportion of patients with bipolar disorder with the requisite clinical and drug level monitoring.
8. The use of clonazepam should be curtailed and it should be used for short term only.

In psychiatric practice, uniform response to medical therapy may not be seen. The drug therapy has to be individualised and the doses may vary, depending on the severity of the condition, medication and the person. Having said that, it is important to follow the standard guidelines and practice evidence-based medicine.

Conflict of Interest: None.

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