Attitudes and subjective reasons of medication compliance and noncompliance among outpatients with schizophrenia in India

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Abstract
Objective: This study aims to assess the attitudes and reasons of medication compliance and noncompliance among patients with Schizophrenia attending outpatients in India and examine the prevalence and factors effecting noncompliance. Method: outpatients with schizophrenia (n=75) and their accompanying family members (n=75) were assessed using standardized tools which consist reasons of medication influences (ROMI) scale, Drug Attitude Inventory (DAI) scale, Positive and Negative Symptoms Scale (PANSS). They were also evaluated for sociodemographic details; illness related and drug related variables. Results: The prevalence of non-compliance in the selected setting is 38.7%. Majority of patients and family members had a positive attitude towards medication and treatment. Family member is able to identify the compliance status of the patient and the reasons for the noncompliance better than the patients. The reasons which are significantly correlating with compliance are ‘perceived daily benefit from medication’, ‘positive relationship with psychiatrist’, pressure from the family and health system’, ‘positive family belief towards illness and treatment’. Where as the significant reasons for noncompliance are ‘no perceived daily benefit from medications’, ‘difficulty in gaining access to treatment and medications’, financial obstacles’, ‘embarrassment or stigma related to treatment and medications’, ‘medicines currently not perceived as necessary’. The factors significantly associated with noncompliance include lower educational status, rural area of stay, adjustment difficulty with their family and spouse, previous history of non-compliance, poor insight into illness, higher positive PANSS score. The patients who gave history of hospitalization in the past are more likely to be compliant with their medication. Conclusions: The Findings strongly recommends the need to develop a standard protocol for carrying out adherence counseling to all patients. Also there is need to create a cadre for mental health nurse practitioner in outpatient and inpatients units to ensure that all patients and family members are given psycho education / adherence counseling before discharge and during follow-ups.

Original work done by the author for the partial fulfillment of the post graduation programme in psychiatric nursing.

Significant outcomes

- Majority of patients and their family member have positive attitude towards antipsychotic medications.
- Patients with higher positive symptoms, poor insight into the illness, rural background, lower educational status, adjustment difficulty with their family and spouse, previous history of non-compliance are more likely to be noncompliant with the medications
- Standard medication adherence counseling protocol need to be developed and used to ensure consistent counseling to all patients before their discharge from inpatient unit and during their follow-up

Limitations

- Self report methods was used to assess medication compliance
- Smaller sample size, and sample of convenience was used
- Patients with irregular follow-ups was not assessed

INTRODUCTION
Medication compliance is one of the most difficult challenges in the management of schizophrenia in India. It is
estimated that the rate of noncompliance is about 50% during first year and 75% during second year, after the patients are discharged from inpatient care unit (1). Medication noncompliance is one of the main obstacles to control relapse in schizophrenia. It significantly increases the rate of relapse, rate and length of hospitalization, and the risk for hospitalization in the future (2). The over all compliance rates for antipsychotic medication was lower than that of antidepressants and other drugs (3).

The medication compliance in patients with schizophrenia had been predicted by the patient’s subjective response to treatment and attitudes towards antipsychotics (4,5). Positive attitude of patients towards treatment can improve therapeutic alliance, medication compliance and long-term prognosis (6). Attitude towards antipsychotic medication is significantly affected by the factors such as lack of insight into the illness, presence of global functioning, increased severity of illness and side effects of medications (7).

Recent studies have shown that the Subjective reasons which are significantly related to medication compliance: ‘perceived daily benefit’, (8,9) ‘positive relationship with the therapist’, ‘positive attitude of significant others’ (9). The reasons identified for patient’s non compliance are ‘distressed by side effects’ (8), ‘lack of insight’ ‘lack of acceptance of treatment’ (9), ‘substance abuse’ ‘low self esteem’, ‘inability to identify the stressors of life’, inability to identify the symptoms of relapse’ (10). Although the burden of side effects is viewed as an important reasons of noncompliance, but studies have found no association between extra pyramidal symptoms and attitude towards antipsychotic medication (6). Its generally believed that atypical antipsychotics are better tolerated by the patients but studies have not found better compliance with these drugs or better effect on the subjective quality of life of patients (6,11,12).

Several studies were conducted to find out the significant predictors of medication noncompliance. These study results have showed that the factors which predict noncompliance are high level of positive symptoms, alcohol abuse (13,14,18), previous noncompliance (13, 14, 19), shorter duration of illness (8), lack of insight(13,15), non affordability of drugs, education not given by doctor(16), young age(17), lower educational level(18), and co morbidity with personality disorder(19).

Majority of these studies are done in developed countries regarding the attitudes and reasons of medication compliance. The current study has tried to assess the attitudes and reasons for compliance as well as noncompliance among patients with schizophrenia, which can provide basis for planning effective interventional strategies to the mental health professionals for improving compliance of the patient in the future.

Aims of the study-To assess the attitudes and reasons of medication compliance and noncompliance among patients with Schizophrenia attending outpatient services in India

Objectives of the study-The objectives of the study are: i) to assess the prevalence of medication non compliance among patients with Schizophrenia, ii) to assess the attitudes towards and reasons of medication compliance and noncompliance, and iii) to identify the relationship of medication noncompliance with demographic and selected variables.

**MATERIALS AND METHODS**

Subjects Seventy five adult patients with schizophrenia and accompanying 75 family members attending the outpatient services of department of psychiatry, All India Institute of Medical Sciences (AIIMS), New Delhi, India from June to November 2006 of, were recruited for the study. Those patients with duration of illness less than 2 years and who are not prescribed any antipsychotics for the past 6 months were excluded from the study. All patients were diagnosed as schizophrenia by the treating psychiatrist as per ICD 10 diagnostic criteria (WHO1992) and are registered in the psychiatry department for the past two years.

**DATA COLLECTION PROCEDURE**

The ethics committee of AIIMS approved the study protocol. All the tools were tried out and pilot study was done prior to actual data collection and found feasible in the proposed setting and population.

Written informed consents were obtained from the patients and their family members after the purpose of the study and risk and benefits of participation had been explained.

Measures evaluated includes sociodemographic details (age of the patient and family member, gender, educational status, marital status, religion, monthly family income, type of family, place of stay, occupation, relationship with spouse/family), illness related variables (total duration of illness, family history, history of hospitalization, duration of
hospital stay, comorbid physical illness, history of substance misuse, insight into illness, severity of illness, frequency of follow up, cost of transport) and medication related variables (number of tablets taken per day, availability of drug, cost of monthly medication, supervision of medication, type of medication, side effects of medication).

Severity of illness was measured using positive and negative syndrome scale (PANSS)(20). It is a 30-item scale (has got a total score of - 210), positive and negative symptom subscale and general psychopathology subscale. The Interrater reliability was established (r=0.82). Subjective reasons of medication compliance/noncompliance were assessed using 20 item ROMI scale (21). The subject was asked to indicate the degree of influence of each item of the scale, i.e. reasons for compliance and reasons for noncompliance. The graduated responses to each are ‘no influence’, ‘mild influence’ and ‘strong influence’ (1, 2 and 3, respectively, or 9 when it is impossible to evaluate the degree of influence). The attitude towards antipsychotic medication was assessed using 30 item drug attitude inventory (DAI) . It is a self report questionnaire in which each item ticked ‘yes’ is rated +1 and items ticked ‘no’ is rated as -1 .The positive scores and negative scores are calculated and the total score will be positive score minus negative score. The positive total score indicates positive attitude and negative total score indicates negative attitude towards antipsychotic medications. DAI and ROMI were administered also to family member accompanying the patient for comparison.

STATISTICAL ANALYSIS

The statistical package for social sciences 10(SPSS Inc., Chicago,IL, USA) program was used for statistical analysis. Data were analyzed using Chi square test, Student’t’ test, Paired’t’ test, and Mann Whitney test.

RESULTS

Out of 75 patients in the study; 46 patients are compliant and 29 patients are noncompliant to the medication and treatment. Hence the prevalence of non-compliance to medication is 38.7%. The patients were defined as compliant, if they take their medications in right doses, frequency as prescribed by the treating psychiatrist more that 23days or 75% of days in the past one month and were defined as noncompliant if they do not take their medications in right doses, frequency as prescribed by the treating psychiatrist or misses the medication for more than seven days continuously or 25% of days in the past one month.

DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

As per the demographic and clinical characteristics are displayed in table 1, the variables that are statistically significant at the level of p>0.05 or below which are significantly related to medication noncompliance are educational status of patient (p=0.03*), from rural background (p=0.02*), adjustment difficulty with the family/spouse (p=0.02*), history of hospitalization (p=0.03*), level of insight into illness (P =0.001**), PANSS positive symptoms score (p=0.02*).

COMPARISON OF ATTITUDE TOWARDS MEDICATION AND TREATMENT USING DAI SCALE

The attitudes of patients towards medication and treatment as measured by drug attitude inventory (DAI) shown in table 2. The patients in the compliant and noncompliant groups have positive overall attitude mean scores. The mean positive attitude, negative attitude and overall attitude of patients towards medication are comparable among both the groups (p=0.2) majority of the patients have positive attitude towards medication irrespective of the compliant/ noncompliance status.

Figure 1

Table 2: Comparison of attitude towards medication between the Patient groups using DAI scale(n+75)

The comparison of the attitudes of patients and family members towards medication and treatment as measured by drug attitude inventory (DAI) shown in table 3. even though majority of the patients and family members, positive attitude towards medication is higher in family member when compared with patient. On the contrary the patient is having more negative attitude towards medication when compared with their family member(p=0.001**).
compliant and noncompliant groups are 1) perceived daily benefits due to medicines ($p=0.01^*$), 2) positive relationship with the treating psychiatrist ($p=0.03^*$), 3) positive family belief towards illness and treatment ($p=0.01^*$), 4) family and health systems pressure on the subjects for taking medications ($p=0.05^*$). Whereas the reasons of relapse prevention and fear of rehospitalization, and are not significantly different among the groups and are comparable.

**Figure 4**

Table 4: Rating of patient’s medication influence (ROMI) scale closed questions (reasons for compliance) ($n=75$)

**REASONS OF NON COMPLIANCE**
The responses to the ROMI open-ended question (what is your main motivation for not taking the medication?) were grouped into thirteen closed questions in the ROMI scale, which is shown table 5. The major reasons of noncompliance which are significantly different among compliant and noncompliant groups are 1) no perceived daily benefits due to medicines ($p=0.02^*$), 2) negative relationship with the treating psychiatrist ($p=0.03^*$), 3) financial obstacles ($p=0.03^*$), 4) embarrassment or stigma related to treatment and medications ($p=0.01^*$), 5) medications currently not necessary ($p=0.03^*$). Whereas the reasons of health professional and friends opposed to treatment and medications, substance abuse, denial of illness, distress due to medications sideeffects, desire to be rehospitalized were comparable between the two groups.

**COMPARISON OF REASONS OF MEDICATION COMPLIANCE AND NONCOMPLIANCE USING ROMI SCALE**

**REASONS OF COMPLIANCE**
the responses to the ROMI open ended question (what is your main motivation for taking the medication?) were grouped into six closed questions in the ROMI scale which is described in table 4. it shows that the major reasons of compliance which are significantly different among

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**Figure 2**
Table 3: comparison of attitude towards medication between patient and family member ($n=150$)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Patient (n=75)</th>
<th>Family Member (n=75)</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive subjective score (mean)</td>
<td>19.8 (SD=4.9)</td>
<td>20.0 (SD=3.8)</td>
<td>t=1.36</td>
</tr>
<tr>
<td>Negative subjective score (mean)</td>
<td>10.6 (SD=4.3)</td>
<td>8.5 (SD=3.8)</td>
<td>t=1.00</td>
</tr>
<tr>
<td>Total attitude score (mean)</td>
<td>5.9 (SD=9.1)</td>
<td>11.5 (SD=7.6)</td>
<td>t=1.85</td>
</tr>
</tbody>
</table>

**Figure 3**
Table 1: the demographic and clinical characteristics of compliant and noncompliant groups $N=75$

**Figure 4**
Table 4: Rating of patient’s medication influence (ROMI) scale closed questions (reasons for compliance) ($n=75$)

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DISCUSSION

This study would be perhaps the first study in India, which measured the attitudes and reasons of patients with schizophrenia about medication compliance on the same subjects. Compliance in this study is defined as the degree to which the patient consistently follows the instruction given by the doctor regarding medication and treatment. For various reasons measuring compliance status accurately is a difficult process as there are different ways to measure compliant status i.e. subjective method and objective method like serum drug levels (8).

In the published literature, demographic variables have not been consistently correlated with medication noncompliance in schizophrenia. It has been found in similar previous studies that younger age group is a significant predictor of noncompliance (22,23). Results of current study showed that there is no significant relationship of the age of the patient and their family member with the compliance. Present study results are in support of the previous findings that there is no significant relationship of gender with compliance (23).

Previous study shows lower treatment compliance in highly educated patients; it could be the result of social disapproval of psychiatric morbidity (24). But in the current study the educational status of the patient is significantly correlating with the medication non compliance, as the majorities (68.8%) of patients in the noncompliant group are educated up to senior secondary school and below whereas as majority (67.4%) of patients in the compliant group are educated senior secondary school and above. This significant difference can be due to the fact that the educational status is significantly correlated to the ability to understand and comprehend the psycho education given by the treating team. The educational statuses of the family member were not significantly related to the compliance as both groups are homogeneous in terms of educational status.

As per the previous studies marital status is significantly related with the compliance and found that married patients are more likely to be compliant (24) there is no significant relationship between marital statuses with the compliance.

Employment predicted a negative attitude towards antipsychotic medication; possibly related to social stigma (6), Majority of patients in current study are unemployed/lost job due to illness in the compliant group and noncompliant group and are not correlated with the noncompliance. Family income was not correlated with noncompliance in this study. This may be due the fact most of the patients are either from poor or lower middle income background, but family members spare money for their patient’s treatment and medication because of the fear of relapse and majority stay in joint family where family support is high.

In the current study majority of the patients in the compliant group (76.1%) stay in urban areas whereas 58.6% of patients in the noncompliant group stay in rural areas. Rural background was significantly related with noncompliance in this study. The main draw back for the patients staying in the rural areas are there are no effective community mental health services available, there is -unavailability of the certain medications, high cost for each follow-up to at the selected setting which is located in urban area. This may be also due to the fact that less number of high education groups in the villages as the educated herds move to cities for employment.

Current study findings revealed that adjustment difficulty of the patients with their family/spouse were significantly related to noncompliance. In these families there will be proper supervision of medication administration or absence of ‘watch dog effect’ of family member upon the patient might partially contribute to the noncompliant behavior of the patient.

Most of the previous studies showed that substance abuse is a strong predictor of noncompliance (13,14,18,25-30), but in the current study the patients in the compliant and noncompliant groups using substances like alcohol and tobacco, which is not significantly correlated to the
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Noncompliance. This percentages may not be the actual percentage because of the fear of the patients that researcher could tell their family and treating psychiatrist about their abuse which may worsen their relationship with them. In addition no objective methods were used to assess the actual substance abuse.

History of noncompliance in the past significantly predicts current noncompliance (29) Previous history of noncompliance is significantly correlated to the medication noncompliance (p=0.01). Ninety seven percent of the noncompliant group had pervious history of noncompliance whereas only eighty-seven percent in the compliant group had history of noncompliance in the past. Even though the compliant group had history of noncompliance, frequent psycho education during the follow-ups might have changed their attitude towards medication and treatment.

Insight into the illness is a strong predictor of compliant behaviors; lack of insight significantly predicts noncompliance (13, 15, 18, 19,30). The current study findings support the previous study findings. Majority of the non-compliant had poor insight (grade1-3)(58,6%).

Other strong predictor of noncompliance is the severity of illness. The current study has used PANSS for assessing the severity. Previous studies showed that higher positive symptom PANSS score (13-15, 18,27) and higher total symptoms score (27,32) predicts noncompliance. In the current study only positive symptom score is found significantly correlated to noncompliance. Increased positive symptoms like hallucination, suspiciousness, and hostility leads to refusal to take medications due to unawareness of the disease and subjective need to rely upon medication (7).

In the current study no significant differences found between the compliant and noncompliant group as per their demographic and selected characteristics like gender, age, employment status, monthly family income, religion, number of daily medicine, medicine availability, duration of illness, medication supervision, cost of medicines, co morbid physical illness, family history of mental illness, frequency of follow-up, and cost of transport. Previous study findings had been contradictory to some of these findings.

The attitude scores of DAI represent an indirect representation of compliance (7). There is a high level of general positive attitude towards medication among patients with schizophrenia (6,11,33). These results are supporting the current study findings, which shows that majority of patients and family members in both the group have positive attitude towards medication. The family member’s high positive belief in treatment and medication might be the reasons for the positive attitude of the patient and increasing the pressure on patient for taking medications, which results in compliance.

Previous studies suggest that the reasons which significantly predict compliance as per the ROMI items are ‘perceived daily benefit’ (8), positive relationship with clinicians and for noncompliance is ‘inconvenience due to side effects.’ (8,9) In the current study the reasons of compliance which are significantly correlated to compliance are ‘perceived daily benefit from medication’, ‘positive relationship with psychiatrist’, pressure from the family and health system’, ‘positive family belief towards illness and treatment’.

Where as the significant reasons for noncompliance are ‘no perceived daily benefit from medications’, ‘difficulty in gaining access to treatment and medications’, financial obstacles’, ‘embarrassment or stigma related to treatment and medications’, ‘medicines currently not perceived as necessary’. While comparing the reasons of compliance/noncompliance given by the patient and family member, there is significant difference between the reasons of patients and that of family members, i.e. the family members are more clearly identifying the patient’s reasons of compliance and noncompliance. Therefore the mental health professional should interview the patient and family members separately to get the clear picture of patient’s compliant behaviors towards medication and treatment.

Previous studies have indicated that fifty to sixty percent of patients with schizophrenia in the outpatient unit are noncompliant to their medication (14,24,31,34,35). In the current study 38.7% of patients are noncompliant to their medication and treatment in the outpatient unit of the selected setting. Even though majority of patients are compliant but, thirty nine percent of the patients still fail to adhere with the prescribed treatment regime, which is an alarming finding and requires great attention. This reflects that the treating team needs to be more committed and should give proper attention to this high-risk group, as they are more likely to relapse in the near future.

Majority of the noncompliant patient are lesser educated, and are staying in rural areas. The follow-up counseling for these patients has limited scope, as it is psychiatrist driven.
who is overburdened with patient load. The family member and patients are reluctant to ask their queries about their medication and treatment and most of the doubts remain unanswered during the follow up. This results in the abrupt cessation of medicines as soon as the patient reaches remission leading to noncompliance and relapse. So these patients need special attention and proper adherence counseling.

At present there is no support group functioning, which may provide services for the family members to solve the issues and burden of the family member and their role in patient care for improving compliance. The study findings strongly recommend the need for starting the of support groups to tackle the problems of the family member in managing their patient effectively. The study findings suggest that standard protocol need to be developed for providing consistent medication adherence counseling for the mental health professionals, which will improve the compliant behaviour of patients towards their medication and treatment.

In conclusion, we have shown that overall patients and their family member have a positive attitude towards medication and treatment, family member is having more positive attitude and are able to identify the reasons of noncompliance better than their patients. The prevalence of noncompliance in the selected is 37.8%, and the factors which significantly related to noncompliance are lesser education status, rural area of stay, adjustment difficulty with family members, higher positive symptoms severity, poor insight and previous noncompliance. These factors should be incorporated into any programme designed to improve overall compliance.

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