

CORRELATION BETWEEN INSIGHT AND ADHERENCE TO TREATMENT IN PATIENTS WITH SCHIZOPHRENIA ATTENDING A TERTIARY CARE CENTER IN CENTRAL INDIA – AN EXPLORATORY STUDY

Manish N. Thakre¹, Sudhir L. Mahajan², Avinash Turankar³, Prachi Jain⁴

¹Assistant Professor, Department of Psychiatry, Government Medical College, Nagpur.

²Senior Resident, Department of Psychiatry, Government Medical College, Nagpur.

³Associate Professor, Department of Pharmacology, Government Medical College, Nagpur.

⁴Research Associate, Department of Psychiatry, Government Medical College, Nagpur.

ABSTRACT

AIM

Schizophrenia is a chronic illness requiring long term treatment adherence. There are many factors affecting the adherence to treatment and insight is amongst the most important factor affecting the adherence. In this study we tried to study the Correlation between Insight and Adherence to treatment in patients with Schizophrenia.

METHODS

This is a cross sectional observational study conducted in the Department of Psychiatry of a tertiary care teaching hospital in Central India. A total of 100 consecutive patients with schizophrenia in remission meeting various inclusion and exclusion criteria were recruited for the study. Socio-demographic and clinical data was collected. Insight was assessed using Sai-E (Schedule for assessment of insight-Expanded) and Adherence was assessed using BARS (Brief Adherence Rating Scale).

RESULTS

The mean Insight score (Sai-E) in non-adherent group was 12.79 (SD:4.04); in partial adherent group was 13.24 (SD:3.727) and in adherent group was 15.19 (SD: 3.324). The correlation between the level of Insight (as assessed on Sai-E) and the degree of adherence was assessed using Spearman's rho coefficient of correlation and the results were statistically significant implying that as the insight scores increases adherence to treatment increase (i.e. positive correlation). There was no statistically significant correlation between Insight and any of the socio-demographic and clinical variables. There was positive correlation between adherence and education (p value:0.02). In the same way there was negative correlation (p value: 0.05) between adherence and illness duration.

CONCLUSION

This is first study from Central India assessing various factors affecting adherence to treatment in Schizophrenia. In our study, insight was found to have positive correlation with treatment adherence. Also, there was positive correlation between adherence and education indicating that higher the education better is the adherence. In the same way there was negative correlation between adherence and illness duration indicating that more the illness duration poorer is the adherence to treatment.

KEYWORDS

Schizophrenia, Insight, Adherence.

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INTRODUCTION: Schizophrenia is a chronic illness requiring long term treatment adherence. There are many factors affecting the treatment adherence. Insight is one such factor affecting the treatment adherence.

Insight is defined as the awareness of having a mental disorder, of its symptoms and of its implications. As per Amador and David 1998,¹ Insight has multiple dimensions

mainly: 1. Awareness of mental disorder, 2. Understanding of social consequences of disorder, 3. Awareness of need of treatment, 4. Awareness of specific signs and symptoms and 5. Attribution of symptom to disorder. It has been shown that 50-57% of patients with schizophrenia had a moderate to severe lack of awareness of mental illness; 32% were markedly unaware of the social consequences of their illness, and 22% denied the need for, or benefit of, medication.^{2,3,4} The WHO International Pilot Study on Schizophrenia showed that lack of insight was the most common symptom of schizophrenia, occurring in 98% of patients.⁵ Impaired insight may be suggestive of a mental process of denial or of neurocognitive impairment. Impaired insight has been also associated with severe psychopathology, poor work performance and poor

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Corresponding Author:

Dr. Manish N. Thakre,

Department of Psychiatry,

Government Medical College and Hospital,

Nagpur-440009, India.

E-mail: drmanishthakre@gmail.com

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treatment outcomes.^{6,7,8,9} Non adherence to treatment leads to more symptomatic state, relapses, substance abuse, and poorer insight into their illness.^{10,11}

Medication adherence is defined as the degree to which medication is taken as prescribed. In patients with schizophrenia medical adherence has often been reported as an all or nothing behaviour i.e. the patient either is adherent or is not. This notion of non-adherence as complete, wilful cessation of all antipsychotic medications is not an accurate representation of actual medication-taking behaviour among outpatient populations with schizophrenia.¹² Assessing this adherence behaviour can be done using objective and subjective measures. Objective measures are blood tests (serum levels of the drug e.g. serum Clozapine levels) and electronic pill counts.^{13,14} Subjective measures rely on assessments made by the patient or a closely involved person such as a clinician, nurse, or caregiver. The most commonly used standardized scale to assess medication adherence is Brief adherence rating scale (BARS).¹⁵

Inter play between insight and adherence to treatment has been investigated in past. While majority of studies are suggestive of positive correlation, some are equivocal.¹⁶ However there are very few studies from India studying this relationship.¹⁷ So, there is a need for the structured study which will assess the correlation between Insight and Adherence to treatment in terms of various socio-demographic variables.

Therefore the present study aimed to study the Correlation between Insight and Adherence to treatment in patients with Schizophrenia attending a tertiary care center in Central India.

METHODOLOGY: This Cross sectional observational study was conducted in the Department of Psychiatry of a tertiary care teaching hospital in Central India. The study was approved by the Institute Ethics Review Committee and all the patients were recruited after obtaining proper written informed consent.

We approached 110 patients of schizophrenia in remission (defined as PANSS score of 3 or less on 8 items as per criteria set for remission by van Os J et al, 2006)¹⁸ and out of which 100 patients were recruited for the study. Diagnosis of Schizophrenia was confirmed using DSM-IV-TR criteria.¹⁹

The Selection Criteria were as Follows:

Inclusion Criteria: Patients age between 18-55years diagnosed to have schizophrenia (as per DSM IV TR), duration of treatment being at least 1 year, in remission at the time of interview and willing to give consent were included in the study.

Exclusion Criteria: Patients suffering from any other psychiatric illness or substance use disorders (except tobacco), not giving consent, not able to comprehend the nature, meaning and importance of questionnaire and communicate appropriately for any reason were excluded.

Procedure: Those who were found to meet the inclusion criteria were briefed about the trial by investigator, after obtaining informed consent. Demographics were collected and study questionnaires were administered. Patients were asked to give details about their medication use over last month.

Instruments:

Insight Assessment: Insight was assessed using Schedule for assessment of insight-Expanded (SAI-E). The SAI was developed for the assessment of insight in psychotic patients and it is based on a concept of insight that encompasses three distinct but overlapping dimensions: 1) recognition of mental illness; 2) ability to relabel unusual mental events (e.g. hallucinations) as pathological; and 3) treatment compliance, both expressed and observed. Afterwards, the SAI has been expanded (SAI-E) to include items on awareness of core symptoms, emotional/psychological changes and difficulties resulting from the mental condition. Total score ranges from 0 to 28. Higher the score greater is insight. We used total score of SAI-E for analysis.^{20,21}

Adherence Assessment: The Brief Adherence Rating Scale (BARS) is a recently developed clinician-administered adherence assessment tool consisting of three questions about the patient's knowledge of their own medication regimen and episodes of missed medication taking, as follows: number of prescribed doses of medication per day, number of days in the past month when the patient did not take the prescribed doses, number of days in the past month when the patient took less than the prescribed dose. A visual analogue scale (VAS) used to assess the proportion of doses taken by the patient in the past month (0-100%). Cronbach's coefficient alpha revealed very high internal reliability for the BARS across the 6 monthly assessment periods ($\alpha=.92$). The BARS also demonstrated good test-retest reliability. The BARS (with a cut-off of 71% for a 6-month monitoring period or 74% mean adherence for an initial 3-month monitoring period) further demonstrated good sensitivity (73%) and specificity (71%-74%) to detect non-adherent electronic monitoring (EM) outpatients (defined as 70% mean adherence of the 6 monthly EM adherence assessments). Score are reported as percentage ranging from 0 to 100. In a recent review of adherence assessment in schizophrenia, Velligan et al. suggested that adherence should be reported as a percentage to allow comparison of adherence studies based on a common metric.^{15,22}

For our study we divided adherence scores in three groups: 1) with 80% above score as good adherence 2) with 50% to 80% as partial adherence and 3) with below 50% adherence score as non-adherence over one month period.

STATISTICAL ANALYSIS: Descriptive analysis was carried out using mean and standard deviation with range for continuous variables. Frequency and percentages were calculated for discontinuous variables. Comparisons of the level of Insight (as assessed on total score of SAI-E) in 3 groups of Adherence (Adherent, Partial adherent, Non

adherent) were done by using one way ANOVA. To examine the association between the Insight (as assessed on SAI-E) and Adherence (as assessed on BARS), Spearman's rank correlation coefficients was used.

RESULTS: One hundred and nine (N=110) consecutive patients diagnosed with Schizophrenia and meeting the remission criteria were approached. Of the 110 patients, 10 patients were excluded based on various exclusion criteria. The final study sample comprised of 100 patients.

The mean age of the study sample was 32.5 (SD-8.61; range-19-53) years. 59% (n=59) of the participants were male. About two- third of the participants (n=65) were married. As regards to the duration of illness, 27% had illness duration less than 2years, 33% patients had illness duration between 2-5years and 40% of patients were having illness for more than 5 years.

The mean Sai-E (degree of Insight) of the study sample was 13.77 (SD-3.85; range 6-21) and on adherence scale (BARS), 42% patients were non adherent (BARS score 0-50), 21% patients were partially adherent (BARS score 51-80) and 37% were adherent (BARS score >80).

Comparison of Insight with Adherence:

Insight (Sai-E) ↓	Non Adherent (BARS 0-50)	Partially adherent (BARS 50-80)	Adherent (BARS >80)
Mean	12.79	13.24	15.19
SD	4.04	3.727	3.324

Table 1

One way ANOVA using Tukey's Multiple Comparison Test	Mean Difference	q	Significant? P < 0.05?	95% CI of diff
non adherent vs partial adherent	-0.4524	0.643	No	-2.825 to 1.920
non adherent vs adherent	-2.403	4.049	Yes *	-4.405 to -0.4016
partial adherent vs adherent	-1.951	2.713	No	-4.377 to 0.4746

Table 2

The mean Insight score (Sai-E) in non-adherent group was 12.79 (SD:4.04); in partial adherent group was 13.24 (SD:3.727) and in adherent group was 15.19 (SD:3.324) as shown in Table 1.

The mean Insight score (Sai-E) was compared across these three groups of adherence using one way ANOVA with Tukey's multiple comparison test (we used Graph Pad Prism version 5-trial for statistical analysis). It was found that there was statistically significant difference in the mean Insight score (Sai-E) of adherent and non-adherent group. The difference was not statistically significant amongst non-adherent & partial adherent group and partial adherent & adherent group.

The correlation between the level of Insight (as assessed on Sai-E) and the degree of adherence was assessed using Spearman's rho coefficient of correlation using Graph Pad Prism version 5.0 (trial) and the results were statistically significant implying that as the insight scores increases adherence to treatment increase (i.e. positive correlation) as shown in Table 3.

Insight vs Adherence	Bars
Sample size	100
Spearman r	0.271
95% confidence interval	0.07284 to 0.4485
P value (two-tailed)	0.0064
P value summary	**
Exact or approximate P value?	Gaussian Approximation
Is the correlation significant? (alpha=0.05)	Yes

Table 3

Correlation of Insight with Various Socio-Demographic and Clinical Variables: We Tried to Find the correlation of Insight (Sai-E score) with various socio-demographic (age, sex, marital status, education, income, working status) and clinical variables (duration of illness, duration of treatment). But there was no statistically significant correlation between Insight and any of the socio-demographic and clinical variables.

Correlation of Adherence with various socio-demographic and clinical variables: We also tried to find the correlation of Adherence (BARS) with various socio-demographic (age, sex, marital status, education, income, working status) and clinical variables (duration of illness, duration of treatment). We found that there was positive correlation between adherence and education (p value: 0.02) indicating that higher the education, better is the adherence. In the same way there was negative correlation (p value: 0.05) between adherence and illness duration indicating that more the illness duration poorer is the adherence to treatment. There was no statistically significant correlation between adherence and other socio-demographic and clinical variables.

DISCUSSION AND CONCLUSIONS: Relationship between Insight into mental illness and adherence to treatment is assumed to be linear. However the results are inconclusive. Measuring insight is affected by quality of insight assessment instrument and subject's psychopathology.²³ In the present study, insight was measured with SAI-E which is one of the standardized instruments widely used to measure Insight.²⁴ In order to reduce bias due to subjects' psychopathology, our study also

focused on a group of outpatients who were considered to be in remission.

Measuring adherence coherently and comparing across studies especially subjective rating of adherence also has similar issues of poorly described, not validated, and susceptible to error, misinterpretation, or distortion. Gold standard electronic monitoring of medication use is often not possible. The Brief Adherence Rating Scale (BARS) is compared against electronic monitoring and is validated. Here the adherence is not seen as an all or none phenomenon.¹⁴

In our study we found a statistically significant difference in the mean Insight score (Sai-E) of adherent and non-adherent group and there was positive correlation with Insight score and adherence implying insight into illness leads to better adherence to treatment in patients with Schizophrenia in remission. If we look at the studies in past, most of the studies have tried to find the association between insight and adherence in patients with acute psychosis or first episode psychosis^{2,3,9} and they have found the same association between insight and adherence.

However, in a review by Lincoln et al in 2007,¹⁶ it is mentioned that this association between insight and adherence fades over time i.e. there are few longitudinal studies comparing insight with adherence over time in patients with Schizophrenia. One such study by Yen et al²⁵ found a correlation between insight and adherence at index interview but not at 1-year follow-up. Similarly, McEvoy et al²⁶ found a trend toward more adherence with outpatient treatment among patients who had insight at discharge for the 30-day follow-up but not for the 2-year follow-up. However, a similar longitudinal study by Novac-Grubic et al²⁷ found a clear association between insight and adherence even at follow up. Our study, although cross sectional have confirmed that even in remission insight play a role in maintaining adherence in patients with Schizophrenia. The clinical implication of these findings is that the patients with poor insight and adherence to medication can be targeted for interventions such as long-acting injectable antipsychotic medication, participation in motivation enhancing therapy, or assertive community treatment.

In our study we did not find any correlation of Insight (Sai-E score) with various socio-demographic (age, sex, marital status, education, income, working status) and clinical variables (duration of illness, duration of treatment). If we compare these findings with previous studies, most studies^{28,29,30,31} show similar results showing no correlation of insight with various socio-demographic variables. However, in one study by McEvoy et al,³² older age and female gender were associated with more insight. But this study was done on patients presenting with first episode psychosis.

The other findings in our study were that we found a positive correlation between adherence and education (p value: 0.02) indicating that higher the education, better is the adherence. These results were consistent with a recent study by Eticha et al³³ which found that being illiterate (AOR=0.13, 95% CI: 0.03, 0.47) was associated with less

medication adherence. The same study also found that the older age group (AOR=0.03, 95% CI: 0.01, 0.16) was associated with less medication adherence. However, studies by Higashi K et al³⁴ and Kane et al,³⁵ concluded that socio-demographic factors of the patients are not consistent predictors of poor adherence.

In the same way there was negative correlation (p value: 0.05) between adherence and illness duration indicating that more the illness duration poorer is the adherence to treatment. These results were in line with few studies in the past.^{30,31}

The strength of our study is that it is the first study from Central India assessing various factors affecting adherence to treatment in Schizophrenia and we specifically selected patients who were in remission. However there is a need for further studies to look into the reasons for non-adherence to treatment so that those factors are addressed in the treatment.

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