
Clinical, social and pharmacological correlates of compliance in Schizophrenia and Bipolar patients

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ABSTRACT:

Objectives: To assess the compliance of psychotic patients in our culture and in relation to some clinical, social and medications-related factors. **Subjects and methods:** The study has been done in Mansoura city, Egypt, on 44 schizophrenic and 26 bipolar patients. They were subjected to: **1-** detailed history taking from both patient and relatives with special emphasis on both medications profile and family background. **2-** Assessment of compliance with "The Clinician Rating Scale" (Kemp et al, 1996) **3-** Assessment of insight with Schedule for Assessment of Insight (SAI) (David, 1990) and, **4-** Abbreviated assessment of family support with emphasis on acceptance-rejection (over-criticism), care-negligence and warm-distant emotions. Statistical analysis included ANOVA and logistic regression analysis. **Results:** Bipolar patients are significantly more compliant than schizophrenics. There were positive correlation between compliance and degree of insight and negative correlation with both age and duration of illness. Atypical antipsychotics, type of care giver, family support and history of folk therapy are among the factors that affect compliance. Logistic regression reveals that the significant predictor factors for compliance are diagnosis, insight and family support. **Conclusion:** Compliance is a complex issue which is affected by illness variables including insight, medication profile and family profile. Improving compliance can be better achieved through tackling all related factors and not dependent on medications only.

During the last few decades, studying compliance and how to improve it among patients has become progressively in focus not only in psychiatric field, but for most physicians as well. Before the year 1975, the term "patient dropout" was commonly used, but it became substituted with the concept of "compliance" (Blackwell, 2000). The most popular definition of compliance was that of Sackett & Hayness (1976) who notified it as the extent to which a person's behavior is in line with the medical advice given. It comprehends a wide variety of behaviors: failure to enter a treatment program, premature termination of therapy, and incomplete implementation of instructions, like drug prescriptions. The problem of non-compliance has been observed among different varieties of patients and not psychotics only. Even, some authors advocated that non-adherence is human nature and not a

result of mental illness (Jarboe, 2002). Ludwig et al (1990) explained compliance according to the "health belief model" in which health behavior is based on the perception of a threat (disease) and the belief that a certain action will reduce this threat. So, the decision to act (i.e. to take treatment) depends on weighing the advantages and negative consequences of the proposed action. However, Kane (1985) stressed that models of compliance borrowed from physical medicine don't fit properly in treatment of psychoses where the perception of illness is often distorted. Nevertheless, noncompliance is still considered a specific problem in psychiatry especially for psychotic patients due to their particular problem of lost or impaired insight into illness which interferes drastically with treatment-adherence with subsequent higher risk for relapse and disease exacerbation (Balon, 2002). Psychotic

disorders imply also other factors that add to the problem of non-compliance such as symptoms like suspiciousness, grandeur delusions (Gaebel & Pietzker, 1985) and disturbances in cognitive functions (Cuffel et al, 1996), as well as chronicity (Balon, 2002). Compliance is also influenced by Medication characteristics e.g. side effects, individual sensitivity to side effects, simple versus complicated medication regime, 2nd versus 1st generation of antipsychotics (Awad et al, 2004), expense of treatment (Blackwell, 2000) and use of long acting and slow release, formulations (Vergouwen et al, 2003). Also, patient's attitude viewing mental health treatment as relatively ineffective and embarrassing will add to his non-compliance (Edlund et al, 2002). Social background of patients is found also to have a significant impact on compliance such as: family awareness about the patient's illness (Smith et al, 1997), supervision (Buchanan, 1992), and family attitude regarding the illness & behavior towards the patient (McFarlane & Lukens, 1998). The reported rates of noncompliance in psychotic disorders show great variations. It was estimated as 80% by Sajatovic et al (2002) and 74% by Awad et al (1999), and in the study of O'Donnell et al (2003), it was 35%. On the other hand, it was also reported to vary between only 11-18% (Ayuso-Gutierrez & Del Rio Vega, 1997). So, it doesn't seem that the introduction of new generation antipsychotics had improved compliance satisfactorily. In Egypt and Arab countries, although not enough data are available, yet, it would be expected that common cultural beliefs about both psychiatric illness and treatment would have their impact on compliance. In this study, we are going to assess the compliance of psychotic patients in our locality, and in relation to some clinical, social and medications-related factors.

SUBJECTS & METHODS:

The study was carried out in Mansoura city, Egypt, during the period from Mars 2004-July 2004. Subjects: To ensure variations in socio-demographic background of the sample, patients were derived from both a state hospital (Mansoura University Hospital) and a private hospital. Patients joined the study soon after controlling florid symptoms and soon after controlling florid symptoms and if they fulfilled the following inclusion criteria:

- 1- DSMIV diagnostic criteria of either schizophrenia or mood disorder (bipolar).
- 2- Agreement to share in the study.
- 3- Minimum duration since the start of psychiatric treatment is one year.
- 4- The patient is living within a family (whether nuclear or extended).
- 5- Availability and willingness of at least one close family member to share in the study. According to these criteria, 70 patients were included in the study. 44 schizophrenics and 26 bipolar mood disorder patients.

Methods: *All patients were subjected to the following:*

1- Semi-structured psychiatric interview with detailed history taking from both patient and relatives with special emphasis on:

- a- Medications profile: type, mono vs polypharmacy, and history of side effects.
- b- Family background: caregiver, participation in treatment intake, opinion about drugs and attendance of folk therapy.

2- Assessment of compliance with "The Clinician Rating Scale" (Kemp et al, 1996), which is an ordinal scale of 1-7, with higher numbers indicating greater adherence (see Appendix I).

3- Assessment of insight with "Schedule for Assessment of Insight [SAI] (David, 1990): it consists of 7 questions, for each answer is: 0, 1 or 2 with maximum score of 14. (Appendix 11).

4- Abbreviated assessment of family support by two raters (two psychiatrists) on a scale covering 3 dimensions: acceptance-rejection (over-criticism), care-negligence and warm-distant emotions. The mean of the two ratings is then categorized as: poor, moderate or good support.

Statistical analysis:

Using the SPSS, both version, data were processed and analyzed through application of Chi square for comparison between percentages, F (ANOVA) test to compare means, r (Pearson correlation coefficient) to find correlation between different continuous variables and logistic regressive analysis to determine the probable predictors of good compliance among all the studied factors.

Results

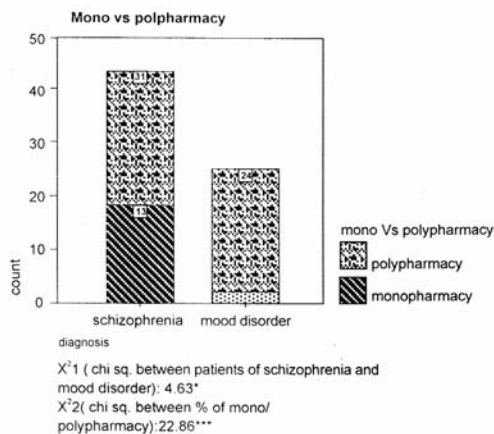
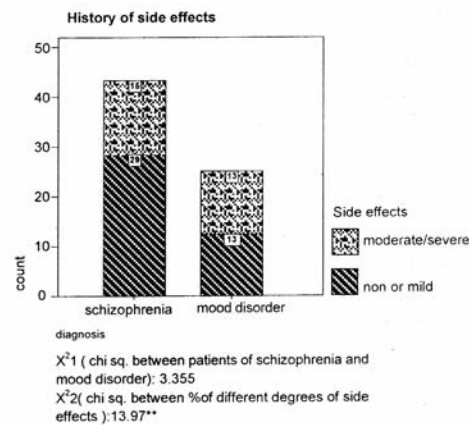
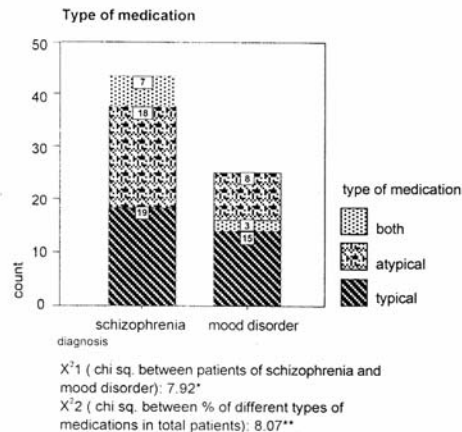
The socio-demographic characteristics of the patients' sample are shown in table (1). As illustrated in Figure (1), only 21 patients were on atypical antipsychotics (30% of patients), the majority of them were schizophrenics (18 patients), while 21.4% of the total sample were on both typical and atypical antipsychotics.

Accordingly, most of patients were receiving polypharmacy (78.6%) as typical antipsychotics are usually administered with anti parkinsonian drugs, but this was more frequent among bipolar patients (24 patients) than schizophrenics (31 patients) i.e. 92.31% & 70.45 respectively.

Table (1): Sociodemographic Profile of the Patients

	Schizophrenia (44)		Mood disorder (26)		Total	
	No	%	No	%	No	%
Age Mean $\pm$ SD	37.18 $\pm$ 12.91		26.58 $\pm$ 10.25		33.24 $\pm$ 12.98	
Sex						
Male	29	65.90	15	57.69	44	62.9
Female	15	34.09	11	42.31	26	37.1
Marital status						
Single	28	63.64	14	53.84	42	60
Married	6	13.63	6	23.08	12	17.1
Widow or Divorced	10	22.73	6	23.08	16	22.9
Residence						
Urban	24	54.54	14	53.84	38	54.3
Rural	20	45.46	12	46.15	32	45.7
Socio-economic Class						
Poor	26	59.09	14	53.84	40	57.1
Intermediate	16	36.36	11	42.31	27	38.6
High	2	4.55	1	3.85	3	4.3
Education						
Illiterate	5	11.36	4	15.38	9	12.9
Primary & Intermediate	5	11.36	5	19.23	10	14.3
Secondary	12	27.27	11	42.31	23	32.9
High	22	50	6	23.08	28	40
Occupation						
Non (& housewives)	22	50	17	65.39	39	55.7
Student	6	13.63	3	11.54	9	12.9
Manual worker	2	4.55	3	11.54	5	7.1
Clerical	9	20.45	0.0	0.0	9	12.9
Professional	5	11.36	3	11.54	8	11.4

Graph 1: Medication Profile of the Patients According to their Diagnosis



NB.: (X^2_1 =(chi sq. between schizophrenies and mood disorder patients)
 X^2_2 = chi sq. between subgroups of each variable among the whole sample

History of sever side effects was mentioned by only 4 patients (5.7% of total patients), while 24 patients (34.3%) had moderate side effects and 60% had no or mild side effects history. For statistical purpose, both sever and moderate side effects were grouped

together constituting 40% of total patients (42 patients: 29 schizophrenics and 13 bipolar). Fig. 2 shows; some family aspects of the patients: the main 'caregiver for 19 bipolar patients was parents (73.07%), while for schizophrenics, it was parents for 15

patients (34.09%) or siblings (20 patients i.e. 45.45%). Also, for 35.71 % of total group (25 patients: 14 schizophrenic and 11 bipolar) of patients, their families were involved with them in following treatment regimen. However, this ratio was higher among families of mood disorder patients as compared to schizophrenics' families (42.31% & 31.82% respectively).

Family support was rated as good among 9 (38.46%) of bipolar patients and 6 (18.18%) of schizophrenics, while moderate support was rated among about half the patients and poor support among 18 (40.90%) of schizophrenics and only 2 (11.54%) of bipolar patients. All these mentioned differences between

schizophrenics and bipolar patients were found to be statistically significant. Relatives of 16 schizophrenics (36.36%) and 5 bipolar (19.23%) perceive medications as harmful, while it was considered as useful by 11 (25%) schizophrenics and 11 (42.31 %) bipolar, and relatives of other patients mentioned that medications are useful but with harmful effects. As regards folk therapy attendance, it was mentioned to be tried at the start of illness by 58.57% of patients, while only 10% (5 schizophrenics and two bipolar) mentioned that they still attend it in association with psychiatric treatment. As shown in Table (2)

**Table (2) Degree of Insight in both Schizophrenic and Bipolar patients
(According to SAI)**

	Schizophrenia		Bipolar disorder		T
	Mean	± SD	Mean	± SD	
Insight Mean ± SD	3.59	3.45	6.65	3.35	3.62 **

** = Sig. at < 0.001

bipolar patients have significant higher score of insight than schizophrenics. Degree of compliance was found to be little higher among females than males , single subjects than married, widow or divorced, rural residents than urban, better educated subjects and students rather than workers. However, most of these variations were minimal and none of them was statistically significant (Table 3). Bipolar patients were found to be of higher compliance (4.5 ± 1.77) than schizophrenics (2.75 ± 2.35) with high statistical significance (Table 4). relatively more compliant (3.68 ± 1.66 , 3.47 ± 2.39 & 3.89 ± 1.86) than those on typical antipsychotics, polypharmacy and history of severe side effects (3.29 ± 2.63 , 3.13 ± 2.03 & 3.28 ± 2.47 respectively). As also, as it is shown in table 3, patients on atypical

antipsychotic, on monopharmacy and with history of none or mild side effects were regards the differences in compliance according to some family factors (table 5) patients whose caregiver was parent showed significant better compliance than others, and followed by patients whose caregiver is a spouse (4.12 ± 1.92 & 3.70 ± 2.54 respectively). Also, when family members (caregivers) were almost participating with patients in following treatment regimen, compliance was better than when this participation was occasional or absent (4.00 ± 2.45 , 3.00 ± 2.63 & 3.52 ± 2.01 respectively). Compliance was found to be higher among patients whose relatives consider medications as "useful" than other patients but without statistically significant difference. Good family support was associated with significant

higher compliance than moderate or poor support (4.93 ± 1.41 , 3.52 ± 2.28 & 2.14 ± 2.19 respectively). Finally, recent attendance of folk therapy i.e in concomitant with psychiatric treatment was associated with poor compliance (2.71 ± 1.38) as compared to those who never tried it or attended it only at the start of illness (3.73 ± 2.55 & 3.34 ± 2.31 respectively). Significant negative correlation was found between degree of compliance with each of patients' age and duration of illness, while degree of insight was positively correlated with compliance with high statistical significance (table 6). Logistic

regression (table Taft) has been done to predict which of all the factors assessed in this study would affect Patients compliance. As shown in table.7-a, clinical diagnosis and degree of insight were the most significant factors ($p < 0.001$), followed by family support ($p < 0.01$), type of caregiver, mono-therapy, degree of education ($p < 0.5$) and history of side effects ($p < 0.09$). When the equation of regression was applied (tab. 7-b), the factors which stood out as the most influential were diagnosis, degree of insight and family support respectively.

**Table (3): Variations in Patients' Compliance (ANOVA test)
According to Socio-demographic characteristics**

Variable	Degree of Compliance Mean $\pm$ SD		F
Sex			
Male	3.34	± 2.41	0.938
Female	3.50	± 2.16	
Marital status			
Single	3.83	± 2.33	0.757
Married	2.81	± 2.08	
Widow or Divorced	2.75	± 2.29	
Residence			
Urban	3.13	± 2.03	1.362
Rural	3.71	± 2.59	
Socio-economic Class			
Poor	3.38	± 2.42	2.07
Intermediate & High	3.24	± 2.22	
Education			
Illiterate Non	3.33	± 2.29	0.986
Primary & Intermediate	2.60	± 2.20	
Secondary & High	4.14	± 2.24	
Occupation			
Non	3.56	± 2.36	0.586
Student	4.67	± 1.50	
Manual worker	3.20	± 2.39	
Clerical & Professional	2.41	± 2.36	

**Table (4): Variations in Patients' Compliance (ANOVA test)
According to Diagnosis and Medication' profile**

Variable	Degree of Compliance Mean $\pm$ SD		F
Diagnosis Schizophrenia Mood Disorder	2.75 4.5	± 2.35 ± 1.77	3.621** Sig. at <0.001
Type of antipsychotics Typical Atypical Both	3.29 3.68 3.38	± 2.63 ± 1.66 ± 2.19	2.613* Sig. at <0.01
Mono vs Polypharmacy Mono Poly	3.47 3.13	± 2.39 ± 2.03	1.001
History of Side effects Non / mild Moderate / sever	3.89 3.28	± 1.86 ± 2.47	1.681

**Table (5): Variations in Patients' Compliance (ANOVA test)
According to Family' profile**

Variable	Degree of Compliance Mean $\pm$ SD		F
Caregiver Parent Spouse Sibs / offspring Others	4.12 3.70 2.22 2.67	± 1.92 ± 2.54 ± 2.50 ± 1.15	2.121*
Participation in drug intake Almost Occasional Never	4.00 3.00 3.52	± 2.45 ± 2.63 ± 2.01	0.602
Family opinion about harmful effects of drugs Useful Useful but Harmful	3.77 3.11 3.38	± 2.29 ± 2.61 ± 1.94	0.493
Family Support Good Moderate Poor	4.93 3.52 2.14	± 1.41 ± 2.28 ± 2.19	2.80** (<0.001)
Attendance of Folk therapy Never At the start of illness Recent	3.73 3.34 2.71	± 2.55 ± 2.31 ± 1.38	2.81** (<0.001)

Table (6): Correlation between Compliance with age of patients, duration of illness and degree of insight

	Mean	±SD	r
Compliance	3.40	±2.31	
Age	33.24	±12.98	-0.390* (<0.05)
Duration of illness	10.71	±8.44	-0.409** (<0.01)
Degree of insight	4.73	±3.70	0.855*** (<0.0001)

Table (7-a): Logistic Regression of all studied factors in relation to compliance

Step 0: Variables not in the Equation

Variables	Score	df	Sig.
Sex	.569	1	.451
Marital Status	.185	1	.667
Residence	.007	1	.934
Education	4.436	1	.035*
Occupation	1.919	1	.166
Socioeconomic	.121	1	.728
Diagnosis	27.416	1	.000***
Type of treatment	.032	1	.859
Mono vs Polypharmacy	3.876	1	.049*
History of side effects	2.789	1	.095
Caregiver	6.160	1	.013*
Participation of family in treatment	0.034	1	.853
Family opinion about harmful effects of drugs	0.229	1	0.633
Family support	10.943	1	.001**
History of folk therapy	2.086	1	.149
Degree of insight	13.641	1	.000***
Overall Statistics	36.238	15	.002

Table (7-b): Logistic Regression of all studied factors in relation to compliance

Step 1: Variables in the Equation

Variables	B	S.E	Sig.
Sex	-.773	1.194	.517
Marital Status	1.213	.849	.153
Residence	.043	.995	.966
Education	-.516	.586	.379
Occupation	.083	.389	.830
Socioeconomic	-.386	1.026	.707
Diagnosis	3.633	1.360	.008*
Type of treatment	-.191	.682	.779
Mono vs Polypharmacy	-.267	1.217	.826
History of side effects	1.764	1.168	.131
Caregiver	-.661	.595	.267
Participation of family in treatment	.732	.851	.390
Family opinion about harmful effects of drugs	1.206	.795	.129
Family support	1.387	.843	.093
History of folk therapy	.648	.767	.398
Degree of insight	1.286	.679	.018*
Constant	-10.747	5.335	.044

Discussion

The problem of compliance doesn't look a well outlined one. Controversy extends to most of its aspects starting from its definition, and ending by the challenge of improving it. Also, debate extends to which factors are in favor of good compliance. In this study, sociodemographic differences among patients didn't show significant impact on compliance although there were some pointers such as female gender, single subjects, students, higher education, and rural residency which were associated with relative better compliance. These findings are close to those of Jellink

(1978), and Smith et al, (1997). Compliance showed significant negative correlation with duration of illness which may be secondary to chronicity effects, boredom and frustration of the patient and his family, while it had strong positive correlation with degree of insight which was found also by McEvoy (1998) and Blackwell (2000). Actually, non-compliance seems to be an ultimate by-product of impaired insight as patients who don't realize that they are ill, will not be willing to take treatment. Ruch and Corrigan (2002) pointed to the impact of both poor insight and lack of medication adherence as leading factors

to the poor outcome of schizophrenia and explained that insight is a multidimensional phenomenon that is derived from many factors such as neurocognitive deficits, psychological coping mechanisms and also lack of awareness. The influence of medications characteristics on compliance has been the focus of many studies. Even, the terminology of "Medications adherence" has become frequently used instead of "compliance", reflecting the extent to which many authors considering therapy the main cornerstone in compliance. Accordingly, much attention has been paid to determine the characteristics of the medication which would encourage patients to be adherent to. Vergouwen et al' (2003) emphasized. 'hat regimen complexity, form, and oute of administration are important factors. Also, Awad and Vourganti (2004) reviewed the results of some concerned studies and concluded that new antipsychotics have superiority in improving medication adherence' behaviour. In agreement, the present study shows that atypical antipsychotics, monotherapy and fewer side effects Were associated with better compliance (statistical significance was only between atypical vs typical or combined medications). However, only 30% of the patients of our study were on atypical antipsychotics secondary to limited income of most patients and lack of health insurance facilities for great proportion of the population. Higher ratio of schizophrenics were on atypical antipsychotics than bipolar patients which may reflects the tendency of psychiatrists to overcome manic symptoms with traditional drugs which were proved to be of benefit in these conditions and which - at the same time - much less expensive. On the other hand, among schizophrenics, and according to the cost-effectiveness perspective, second generation antipsychotics have its role to help in reducing the threat of

chronicity and life long negative symptoms with its enduring disabling effect. The present study has shown that not only medications that have a major impact on compliance, but rather, family background and attitudes were also shown to be mostly significant. When the caregiver was parent or -to a lesser extent- spouse, compliance was significantly better, which is explained by the natural caring attitude of parents and the need of the spouse to regain stability to their nuclear family.

Degree of family support was also found to be significantly affecting compliance. Olfson et al (2000) had found that refusal by patients' families to become involved in treatment predicted patients' non-compliance. Families of psychotic patients have a direct impact on enhancing compliance through supervising their treatment regimen while lacking insight and motivation to take their treatment. Also, positive family attitude minimize the sense of stigma for the patient and so, it can be considered as a healthy environment which provokes the patient to get back to normal life. The over propagation of folk therapy, traditional healers and spiritual treatment of various psychiatric disorders has become a real serious problem that interferes with early detection of diseases, early intervention and appropriate management. In this study, folk therapy was also found to affect compliance negatively. Patients whose families tried to treat them by folk therapy showed poorer compliance than those who didn't try it.

The worst compliance was among those who were still attending folk therapy besides psychiatric treatment which reflects the hesitant attitude of families and their feeble belief in treatment which spread its shadows on the patients' attitude towards treatment and hence compliance. Bipolar patients showed higher Compliance than schizophrenics. The nature of both disorders is highly

related to this issue specially in relation to the course. Other major factor is the degree of insight which was much affected among schizophrenics than bipolar patients (although bipolar patients joined this study just after control of florid symptoms and so, insight is not expected to be fully regained). Blackwell (2000) presented some other factors which may interfere with compliance among schizophrenics: impaired concentration, poor memory, thought disorder and delusional ideas that can erode the trust necessary for a working alliance. Also, depression, apathy, and the negative symptoms of schizophrenia are barriers to the motivation and persistence necessary for long-term treatment. Another factor that may add to the better compliance of bipolar patients than schizophrenics is family background. As compared to schizophrenics, bipolar patients, in this study, enjoy satisfactory family support and an overall positive family attitude. The difference between family profiles of patients of both diagnoses could emerge from different roots: firstly, caregivers of bipolar patients were mostly parents who are usually keen enough on their children' status, secondly, genetic factor should be considered as it is expected that families of bipolar patients are more affectionate. Also, the nature of bipolar disorder, being mostly periodical with free periods, leads the family to be more enthusiastic towards patient' management to overcome the episode and achieve a new remission. To the contrary, chronicity of schizophrenia as well as genetic constitution that may be existent among their families may interfere with good family support and persistent positive attitude towards the patient. From the presented data, it is clear that there is some sort of overlap between different factors affecting compliance, and so, all these overlapping factors were subjected to logistic

regression so as to evaluate their relative predictive value for compliance and the significant factors were found to be: Diagnosis, degree of insight, family support, type of care giver, education, monotherapy, and history of side effects. However, the net conclusion of this analysis was that diagnosis followed by degree of insight and then family support were the most influential for compliance (Tab. 7-b). To conclude, compliance can't be dealt with as a direct result of one or more factors, but rather, it is an attitude which is continuously affected by all intervening factors. Blackwell (2000) notified that most research is cross-sectional, while life is longitudinal and that an individual's compliance may alter radically across the but doctors who should comply with their patients' informed and considered desires and needs".

Limitations & recommendations

The present study represents a screening for many of factors that were expected to influence compliance: disease factors, family and medications profile, and so, some details were lacking for each of them. Also, the inclusion of two diagnostic categories makes some confusion in interpreting the results. Accordingly, the followings are recommended:

- 1- To perform further studies on specific diagnostic category.
- 2- Longitudinal studies should be concerned and,
- 3- culture-based compliance and insight improving programs and family intervention have to be designed and come in focus.

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المخلص العربي

العلاقة بين الالتزام العلاجي والعوامل الإكلينيكية

والاجتماعية الدوائية عند مرضى الفصام

والاضطراب الوجداني ثنائي القطبية

يهدف هذا البحث إلى دراسة الالتزام العلاجي للمرضى الذهانيين والعوامل المختلفة التي تؤثر عليها . تم عمل الدراسة بمدينة المنصورة واشتملت عينة البحث على ٤٤ مريضاً فصامياً و ٢٦ مريضاً بالاضطراب الوجداني وقد تم عمل لهم ما يلي :

١- مقارنة إكلينيكية مع المرضى و ذويهم المقربين مع التركيز على التاريخ العلاجي والخلفية الأسرية .

٢- تقييم درجة الالتزام العلاجي لدى المرضى .

٣- تقييم درجة البصيرة لدى المرضى .

٤- تقييم مختصر للدعم الأسري للمرضى .

وقد أظهرت الدراسة ما يلي:

١- مرضى الاضطراب الوجداني أكثر التزاماً بالعلاج عن الفصامين

٢- توجد علاقة ارتباطية موجبة بين درجة الالتزام العلاجي ودرجة البصيرة وعلاقة ارتباطية عكسية مع عمر المريض ومدة المرض و هي علاقات ذات دلالة إحصائية

٣- يتأثر الالتزام العلاجي المريض بالدعم السري ودرجة قرابة المريض بالمستول عن رعايته علاجياً وأتضح أن الوالدين والأزواج هم أكثر عوناً لذويهم المرضى .

٤- يتأثر الالتزام العلاجي للمريض أيضاً بأنواع العقاقير التي يتناولها وإن كان سبق وتعرض لأثار جانبية لهذه العقاقير أم