

USE OF A TWO-WAY COMMUNICATION QUESTIONNAIRE IN ANTIPSYCHOTIC THERAPY: AN ANALYSIS OF TWO OBSERVATIONAL STUDIES ON DIFFERENCES IN UNDERSTANDING OF INDIVIDUAL PATIENT NEEDS BETWEEN PHYSICIANS AND PATIENTS TREATED WITH QUETIAPINE FUMARATE (SEROQUEL®)

UTILITÉ DU QUESTIONNAIRE 2-COM DANS LA THÉRAPIE ANTIPSYCHOTIQUE: ANALYSE DE DEUX ÉTUDES SUR LES DIFFÉRENCES DE COMPRÉHENSION ENTRE MÉDECIN ET PATIENT CONCERNANT LES BESOINS DU PATIENT SOUS TRAITEMENT PAR FUMARATE DE QUÉTIAPINE (SEROQUEL®)

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COMMUNICATION BETWEEN PSYCHOTIC PATIENT AND HEALTHCARE PROFESSIONALS IS ESSENTIAL FOR OPTIMAL CLINICAL CARE AND DISEASE MANAGEMENT OF THESE PATIENTS. TWO OBSERVATIONAL STUDIES WERE DESIGNED TO EVALUATE THE RESULTS OF QUETIAPINE FUMARATE (SEROQUEL®) IN CONJUNCTION WITH THE TWO-WAY COMMUNICATION (2-COM) QUESTIONNAIRE. THE OBJECTIVE WAS TO OBTAIN DEEPER INSIGHT IN THE PERCEPTION OF EFFECT OF QUETIAPINE FUMARATE AS EXPERIENCED BY PATIENTS WITH BIPOLAR MANIA OR SCHIZOPHRENIA AND THEIR PHYSICIAN. THE RESULTS ON QUESTIONNAIRE SHOWED THAT INVESTIGATORS RATED A HIGHER NUMBER OF NEEDS THAN PATIENTS, BUT THE NUMBER OF NEEDS RATED BY BOTH PATIENT AND INVESTIGATOR DECREASED OVER TIME. A SIGNIFICANT INCREASE IN THE NUMBER OF CONCORDANCES BETWEEN PATIENTS AND INVESTIGATORS WAS ALSO OBSERVED OVER TIME. IMPROVED COMMUNICATION WAS ASSOCIATED WITH AN IMPROVEMENT IN ILLNESS SEVERITY USING THE CLINICAL GLOBAL IMPRESSION SCALE.

Key words : Bipolar Mania, Schizophrenia, 2-COM, Quetiapine fumarate

INTRODUCTION

Schizophrenia and bipolar disorder are two chronic and disabling disorders, each with a worldwide prevalence of 1% (American Psychiatric Association, 1994). Bipolar disorder was ranked as one of five leading causes of 'years of life lived with disability in 15-44 year olds' (World Health Organization, 2001). This disorder is characterised by recurring manic (bipolar mania) and depressive symptoms (bipolar depression) and often psychosis. Bipolar disorder is also associated with high suicide rates and significant social dysfunction (Woods, 2000; Kupfer et al., 2002; Sajatovic, 2005). Schizophrenia is characterised by two classes of symptoms: positive, which include hallucinations, delusions that are often paranoid, disorganised thought and behaviour; and negative, such as flattened mood, poverty of speech, loss of a sense of pleasure, loss of will or drive and social withdrawal (American Psychiatric Association, 1994; Schultz et al., 2007).

One third of patients with bipolar disorder are either not treated in an optimal way or not treated at all, despite the fact that long-term medicinal treatment has been shown to lower suicide rates (Angst et al., 2002). A recent long-term follow-up study showed that patients with bipolar disorder were symptomatically ill about half of the time (47.3% of weeks) throughout a mean of 12.8 year of follow-up (Judd et al., 2002). A similar failure of therapy is seen in patients with schizophrenia. Optimal therapy of schizophrenia is associated with approximately 15% of patients showing acute flares per year; in practice 40-50% of the patients show acute flares (Kissling et al., 1999).

One of the important factors for successful treatment is therapy adherence. Patients using antipsychotic drugs in general have a poor therapy adherence and tools to enhance therapy adherence should lead to an improvement of therapy results and a reduction in overall costs, especially costs of

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hospitalisation during acute flares. Research has shown that therapy adherence is a multidimensional entity that is composed of factors that center on the patient, the care provider and the care system (Sajatovic et al., 2006).

The two-way communication (2-COM) questionnaire was designed to improve communication between patient and psychiatrist (van Os et al., 2002). It is a useful instrument as it allows patients to be more vocal about their problems, provides a better understanding of issues encountered by patients and encourages a clearer communication between patient and carer (van Os et al., 2002). In non-affective manias, the 2-COM has been shown to improve communication between patient and treating physician and in some cases provides needs-related changes in treatment immediately after its intervention (van Os et al., 2004).

In the present analysis, the 2-COM questionnaire was used to assess the difference in disease perception in two observational studies in patients with bipolar mania (Seroquel in *Mania: Real-Life Assessment of Global Disease* perception or 'SMARAGD' study) and schizophrenia (Seroquel *Assessment Follow-up In Real-life* or 'SAFIR' study). The patients in the two studies were treated with quetiapine fumarate (Seroquel®, AstraZeneca).

Quetiapine fumarate (Seroquel®) is an atypical antipsychotic licensed worldwide for the treatment of schizophrenia and acute bipolar mania. The US Food and Drug Administration has also approved the use of quetiapine for the treatment of bipolar depression. Randomised, double-blind trials showed that quetiapine is effective against both positive and negative symptoms of schizophrenia and has benefits in improving cognitive function, affective symptoms and reducing aggression and hostility, even in hard-to-treat patients. Overall, quetiapine showed an excellent risk/benefit profile. It is associated with placebo-level incidence of extrapyramidal symptoms, does not elevate plasma prolactin levels and has minimal short-term effects on body weight (Buckley, 2004; Cheer et al., 2004; Larmo et al., 2005; Miodownik et al., 2006; Pini et al., 2006; Keating et al., 2007).

METHODS

STUDY DESIGN

SAFIR (schizophrenia) and SMARAGD (bipolar mania) were two multicentric observational studies that were conducted in Belgium. These studies were approved by the independent ethics committees of all participating centres and conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Written informed consent was obtained from all the patients prior to study entry.

The objective of these two studies was to get a better insight into the differences, between the patient and the investigator, in the perception of the effect of treatment with quetiapine fumarate (Seroquel®, AstraZeneca, Södertälje, Sweden) over a period of 8 weeks (primary objective) and 6 months (secondary

objective) by using a modified 2-COM questionnaire. Because of the non-interventional study design, no restriction was made with respect to quetiapine fumarate dosage and concomitant use of antipsychotic medication except that treatment had to be in accordance with the scientific leaflet of quetiapine. The studies consisted of three visits: start of treatment (Visit 1), after 8 weeks of treatment (Visit 2) and after 6 months of treatment (Visit 3). Before each visit, the patient and the investigator filled in the 2-COM questionnaire independently. In addition, the Clinical Global Impression (CGI) scale was used by the investigator to determine the severity of disease.

POPULATION

Male and female adult patients, 18 years of age or older, clinically diagnosed with either schizophrenia or bipolar mania were enrolled in the studies. Eligible patients included individuals who were to start on quetiapine fumarate treatment due to intolerance, inefficacy or unwillingness to continue with previous treatment or following a recent diagnosis of either schizophrenia or bipolar mania. Patients treated with clozapine and who were intolerant to this medication; patients who had already received quetiapine fumarate; and patients with a serious underlying condition (e.g. kidney or pancreatic insufficiency, serious heart or vascular disease) were ineligible for enrollment.

2-COM QUESTIONNAIRE

The 2-COM questionnaire was designed to improve communication between patient and psychiatrist (van Os et al., 2002). The 2-COM is a simply phrased questionnaire which lists common problems that might be related to symptoms of the illness, antipsychotic medication or general problems that the patient might encounter on a day-to-day basis; these include accommodation and looking after the house, self care, daytime activities, physical health, psychotic symptoms, information about treatment, relationships, sexuality, transport, money and benefits. The original 20-item 2-COM questionnaire (van Os et al, 2002) was slightly modified by inverting the form of three items, (questions 11, 13 and 18) expressing positive evaluation in order to align them with the other questions, and removing one question (question 20) from the questionnaire used for SAFIR. Each question had 2 parts: (a) "Is this a problem to you?" and (b) "Would you like to talk about it?" A 5-point response scale from 1 = 'never' (no problem); 2 = 'seldom', 3 = 'sometimes', 4 = 'often' to 5 = 'always' (severe problem) was used to respond to part a, with a yes/no answer requested for part b.

The total needs score, based on the responses to part a, was calculated as the sum of the 20-item scores for the SMARAGD study and ranged from 20 to 100. In the SAFIR study, the items score ranged from 19 to 95. A problem was considered as 'reported' and 'detected' when either the patient or the investigator gave the item a score > 1, respectively. Answers by the patient and the investigator were considered as 'concordant' when item ratings were equal for both patient and investigator.

CLINICAL GLOBAL IMPRESSION (CGI)

The CGI is a scale used to assess treatment response in psychiatric patients. It is comprised of three modules, Severity of Illness, Global Improvement, and Efficacy Index. However, for the SAFIR and SMARAGD studies, only the first two modules were used.

CGI-Severity of Illness

The Severity of Illness item required the investigator to rate the severity of the patient's illness at the time of assessment, relative to the investigator's past experience with patients who had the same diagnosis. Considering total clinical experience, a patient was assessed on severity of mental illness at the time of rating on a 7-point scale: normal (1) (not at all ill); borderline mentally ill (2); mildly ill (3); moderately ill (4); considerably ill (5); severely ill (6); or extremely ill (7).

CGI-Global Improvement

The Global Improvement item required the investigator to rate how much the patient's illness had changed over the course of the studies. Compared to condition at Visit 1, a patient's illness was rated according to the following categories: very much improved; much improved; minimally improved; no change; minimally worse; much worse; or very much worse.

DATA COLLECTION

Eligible patients were scheduled to attend 3 visits. At Visit 1, age, gender, body weight, disease history, reason for starting treatment with quetiapine fumarate, concomitant medication and CGI and 2-COM assessment were recorded. At Visit 2 and at Visit 3, CGI, 2-COM, body weight, treatment compliance as well as data on adverse events and concomitant medication were collected.

STATISTICAL ANALYSIS

For the primary objective in each study, 552 patients were needed to achieve a 5% significance level and 90% power to be able to demonstrate a difference of 0.2 times standard deviation (level considered as without clinical relevance) using the Wilcoxon signed rank test. Allowing for early discontinuation of 15% of the enrolled patients and taking into account that 5% of data of the remaining patients would be incomplete or unusable, target enrollment was 684 patients per trial.

Data collected from the modified 2-COM questionnaire completed by the patient were compared with the corresponding 2-COM data from the investigator. Since answers were given on an ordinal scale, comparison was performed using the Wilcoxon signed rank test.

RESULTS

CHARACTERISTICS OF THE STUDY POPULATION

Because enrollment was slower than anticipated, inclusion of patients into the studies was terminated when a total of 648 and 443 patients were enrolled in SAFIR and SMARAGD, respectively.

The demographic characteristics of the patients enrolled in the two studies are given in Table I. Out of the 648 patients in SAFIR, 274 were women and 355 were men (gender was not recorded for 19 subjects). The mean age was 38.7 ± 13.4 years and the mean disease history was 8.6 ± 9.2 years (median: 5 years, range: 0-44 years). For two patients, data was only available for one of the two follow-up visits. Study data from these two patients were excluded from all results and analyses except the safety analysis.

Table I
Demography (at inclusion)

	Characteristics	Age (Mean \pm SD, years)	Weight (Mean \pm SD, kg)	Disease history (Mean \pm SD, years)
SAFIR (Schizophrenia)	Total	38.7 (\pm 13.4) n = 635	76.2 (\pm 15.1) n = 590	8.6 (\pm 9.2) n = 590
	Male	37.0 (\pm 13.4) n = 351	79.6 (\pm 14.2) n = 336	8.0 (\pm 9.1) n = 325
	Female	41.2 (\pm 13.3) n = 269	71.5 (\pm 15.4) n = 242	9.5 (\pm 9.5) n = 250
SMARAGD (Bipolar Mania)	Total	43.2 (\pm 13.4) n = 435	74.7 (\pm 16.0) n = 400	8.5 (\pm 9.3) n = 366
	Male	41.5 (\pm 13.4) n = 178	80.4 (\pm 14.8) n = 164	8.0 (\pm 9.4) n = 146
	Female	44.4 (\pm 13.3) n = 245	70.3 (\pm 15.8) n = 224	8.7 (\pm 9.1) n = 210

In SMARAGD, out of the 443 patients, 179 were men and 251 were women (gender was not recorded for 13 patients). The mean age was 43.2 ± 13.4 years and the mean disease history was 8.5 ± 9.3 years (median: 5 years, range: 0-50 years).

In SAFIR, 20.3% of the patients were being treated for a first antipsychotic episode and 79.7% switched from other treatments to quetiapine fumarate. In SMARAGD, 34.6% (data were missing for 9 patients) were being treated for a first antipsychotic episode and 65.4% switched to quetiapine fumarate from other treatments.

COMPLIANCE WITH STUDY VISITS AND TREATMENT

Of the 646 and 443 patients included in the SAFIR and SMARAGD analyses, respectively, 581 (89.9%) and 391 (88.3%) returned for Visit 2, with 467 (72.3%) and 318 (71.8%) returning for Visit 3. The mean dose of quetiapine fumarate was comparable at Visit 3 compared to Visit 2 in both studies. The mean dose administered in SAFIR was 503.1 ± 278.7 mg/day and 518.1 ± 288.6 mg/day for Visit 2 and Visit 3, respectively. In SMARAGD, the mean dose administered was 471.6 ± 274.4 mg/day and 479.7 ± 294.4 mg/day for Visit 2 and Visit 3, respectively. In these studies, the majority of patients (73.7% at Visit 2 and 74.3% at Visit 3 in SAFIR, and 77.2% at Visit 2 and 78.0% at Visit 3 in SMARAGD) were compliant to treatment.

EVALUATION OF PATIENT NEEDS USING THE 2-COM QUESTIONNAIRE

Table II shows the mean number of needs reported by the patients and the mean number of needs reported by the investigators for the two studies. The score of needs reported by the patient and the score of needs anticipated by the investigator decreased from Visit 1 to Visit 3 (Table II). The investigator scored a higher mean number of needs than the patients themselves at each visit. A logistic regression analysis showed a statistically significant difference between needs identified by

patients and investigators for both studies at all visits except for Visit 3 in SMARAGD. The comparative analysis between visits showed that the degree of concordance between answers for each of the items of the 2-COM questionnaire provided by the patient and the investigator increased with time (p-value <0.0001 using Wilcoxon signed rank test).

ASSESSMENT OF THE ILLNESS SEVERITY AND IMPROVEMENT OVER THE COURSE OF THE STUDY USING THE CGI

Data pertaining to the severity of illness at inclusion are presented in Table III. Data were not available (not evaluated) for 3 patients in the SMARAGD study (bipolar mania) and for 16 patients in the SAFIR study (schizophrenia). The mean CGI value was 4.44 for patients in the SAFIR study and 4.60 for patients in the SMARAGD study at baseline. After 8 weeks of treatment, the CGI value decreased in both studies, and was further decreased at Visit 3. For both studies, improvement observed in severity of illness was statistically significant at each visit (Wilcoxon signed rank test, p-value <0.0001).

The majority of patients showed an improvement during the course of both studies (Table IV). In SAFIR, the percentage of patients falling into one of the 3 'improvement' categories (i.e. very much improved, much improved or minimally improved) was 83.8% at Visit 2 and 84.4% at Visit 3. In SMARAGD, the percentage of patients showing improvement was 81.4% and 82.7% for Visit 2 and Visit 3, respectively.

CORRELATION BETWEEN CGI SCORES AND 2-COM QUESTIONNAIRE

In order to ascertain that there was a correlation between CGI scores and the responses to the 2-COM questionnaire, a correlation analysis was performed at each visit using the Spearman rank correlation test.

All the 2-COM variables were found to be positively correlated (Spearman's coefficient >0.1) with the CGI-Severity of

Table II
Mean number of needs and total needs scores

		SAFIR (Schizophrenia)			SMARAGD (Bipolar Mania)		
		Visit 1	Visit 2	Visit 3	Visit 1	Visit 2	Visit 3
Reported by patient		N = 547	N = 487	N = 399	N = 392	N = 337	N = 264
	Number of needs	15.9 (\pm 3.1)	15.5 (\pm 3.4)	15.3 (\pm 3.8)	16.9 (\pm 3.5)	16.7 (\pm 3.6)	16.0 (\pm 4.1)
	Total needs score	58.5 (\pm 12.2)	52.3 (\pm 11.0)	48.5 (\pm 10.5)	62.5 (\pm 13.9)	56.0 (\pm 12.8)	51.8 (\pm 12.5)
Anticipated by investigator		N = 569	N = 501	N = 407	N = 410	N = 351	N = 277
	Number of needs	17.0 (\pm 2.5)	16.6 (\pm 2.9)	16.2 (\pm 3.4)	17.7 (\pm 2.6)	17.3 (\pm 3.3)	16.4 (\pm 3.7)
	Total needs score	60.1 (\pm 10.2)	52.9 (\pm 10.3)	49.6 (\pm 10.4)	63.6 (\pm 11.6)	56.0 (\pm 11.7)	51.2 (\pm 11.2)
Odds Ratios) (95%CI)	Number of needs	0.86 (0.83-0.91) p-Value <0.0001	0.90 (0.86-0.94) p-Value <0.0001	0.93 (0.90-0.97) p-Value = 0.0006	0.91 (0.87-0.96) P-Value = 0.0002	0.95 (0.91-0.99) P-Value = 0.0296	0.97 (0.93-1.02) P-Value = 0.2149

Logistic regression analysis performed by rater (patient or investigator) for each individual visit.

Illness scores, except the number of needs reported by patient at Visit 1 in SMARAGD and Visit 1 and 2 in SAFIR and the number of needs reported by investigator at Visit 1 in SAFIR. This result shows that a relatively more ill patient had a higher

score of needs. There was a stronger correlation between the CGI score and the patient needs reported by the investigator compared to the patient needs reported by the patient himself.

Table III
Clinical Global Impression-Illness Severity for SAFIR and SMARAGD studies

	Point value	SAFIR (Schizophrenia)			SMARAGD (Bipolar Mania)		
		Visit 1	Visit 2	Visit 3	Visit 1	Visit 2	Visit 3
Normal, not ill	1	N = 646 1 (0.2%)	N = 581 21 (3.6%)	N = 467 23 (4.9%)	N = 443 6 (1.4%)	N = 391 17 (4.4%)	N = 318 24 (7.6%)
Borderline mentally ill	2	20 (3.1%)	55 (9.5%)	69 (14.8%)	7 (1.6%)	31 (7.9%)	44 (13.8%)
Mildly ill	3	111 (17.2%)	153 (26.3%)	138 (29.6%)	68 (15.4%)	116 (29.7%)	108 (34.0%)
Moderately ill	4	159 (24.6%)	166 (28.6%)	114 (24.4%)	110 (24.8%)	111 (28.4%)	61 (19.2%)
Marked ill	5	187 (28.9%)	101 (17.4%)	68 (14.6%)	137 (30.9%)	60 (15.4%)	38 (12.0%)
Severely ill	6	137 (21.21%)	66 (11.4%)	35 (7.5%)	94 (21.2%)	39 (10.0%)	26 (8.2%)
Extremely ill	7	15 (2.3%)	5 (0.9%)	5 (1.1%)	18 (4.1%)	4 (1.0%)	3 (0.9%)
Not evaluated		16 (2.5%)	14 (2.4%)	15 (3.2%)	3 (0.7%)	13 (3.3%)	14 (4.4%)
Mean value		4.44	3.77	3.46	4.60	3.66	3.29

Table IV
Clinical Global Impression-Global Improvement for SAFIR and SMARAGD studies

	SAFIR (Schizophrenia)			SMARAGD (Bipolar Mania)		
	Visit 2	Visit 3	Last evaluation*	Visit 2	Visit 3	Last evaluation*
	N = 581	N = 467	N = 584	N = 391	N = 318	N = 394
Very much improved	41 (7.1%)	59 (12.6%)	68 (11.6%)	34 (8.7%)	58 (18.2%)	65 (16.5%)
Much improved	214 (36.8%)	218 (46.7%)	258 (44.2%)	118 (30.2%)	129 (40.6%)	152 (38.6%)
Minimally improved	232 (39.9%)	119 (25.5%)	160 (27.4%)	166 (42.5%)	76 (23.9%)	109 (27.7%)
No change	49 (8.4%)	32 (7.1%)	43 (7.4%)	34 (8.7%)	19 (6.0%)	27 (6.9%)
Minimally worse	11 (1.9%)	12 (2.6%)	15 (2.6%)	6 (1.5%)	6 (1.9%)	8 (2.0%)
Much worse	17 (2.9%)	18 (3.9%)	28 (4.8%)	16 (4.1%)	15 (4.7%)	20 (5.1%)
Very much worse	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.9%)	3 (0.8%)
Not evaluated	17 (2.9%)	8 (1.7%)	12 (2.1%)	17 (4.3%)	12 (3.8%)	10 (2.5%)

* Using last evaluable evaluation, including patients discontinuing study prematurely.

A positive correlation was also observed between the total needs score and the CGI-Global Improvement scores, i.e. the fewer the number of needs, the greater the improvement in clinical illness over the course of the trial.

SAFETY AND TOLERABILITY OF QUETIAPINE FUMARATE TREATMENT

A total of 210 patients in SAFIR and 116 patients in SMARAGD spontaneously reported at least one adverse event (AE). The most frequently reported AE was weight gain, which was reported with a similar frequency in both studies (20.9% in SAFIR and 18.4% in SMARAGD). In SAFIR, the mean weight increase during study (from Visit 1 to Visit 3) was 1.9 ± 5.7 kg in men and 2.1 ± 7.6 kg in women. In SMARAGD, this increase was 0.3 ± 6.3 kg in men and 1.2 ± 6.9 kg in women.

The other most frequently reported AEs were fatigue (14.7% in SAFIR and 9.8% in SMARAGD) and a feeling of sedation (10.3% in SAFIR and 16.5% in SMARAGD).

Extrapyramidal symptoms of mild to moderate intensity were reported by only three patients in SAFIR and one patient in SMARAGD.

During the course of treatment, one patient committed suicide by means of a multiple drug overdose. The patient had a history of hospitalisation for depression and had attempted suicide 2 weeks previously. As the quantity of quetiapine taken at the time of suicide is unknown, and in the absence of any toxicological assessment, a potential role of quetiapine in the death of this patient cannot be determined.

DISCUSSION

The effectiveness of quetiapine fumarate treatment alone has been demonstrated in different placebo-controlled studies (Buckley, 2004; Vieta et al., 2005). SAFIR and SMARAGD were designed to evaluate quetiapine fumarate treatment in conjunction with the 2-COM questionnaire in adult patients with schizophrenia or bipolar mania.

Both studies showed a significant improvement in the severity of the illness over the both the 8-week and the 6-month observation periods, as determined by the CGI-Severity of Illness assessment. The number of needs, as evaluated by both the investigator and the patient, also significantly decreased over the course of the study. The degree of improvement was higher than that observed following administration of quetiapine fumarate treatment alone in similar groups of patients.

In a previous observational study on patients with schizophrenia who completed the 2-COM questionnaire prior to routine appointment, both physicians and patients found the checklist useful (van Os et al., 2002). In addition, patients, but not clinicians, considered that the checklist had resulted in a change in treatment. The results also indicated that the 2-COM questionnaire was most highly regarded by those patients with the highest number of care needs, suggesting 2-COM captures

negative appraisals associated with perceptions of care (Hansson et al., 2007). In a subsequent randomised controlled trial, it was shown that using the 2-COM questionnaire induced a stable improvement of patient-reported quality of physician/patient communication over a period of six weeks, and induced changes in management immediately after the intervention (van Os et al., 2004).

This enhancement may have been triggered by the improved communication between the patient and the investigator with the help of the 2-COM questionnaire, which will have allowed the investigator to make any changes in treatment based on the patient needs and may have also allowed the patient to feel more involved in the treatment process as well as being treated with respect, thus encouraging adherence to therapy.

Patient expectations and treatment alliance in pharmacotherapy have been shown to be predictive of outcomes in bipolar disorder (Gaudiano et al., 2006). The use of a patient completed questionnaires on symptoms and problems in treatment planning has also been shown to result in improved patient commitment to treatment and patient satisfaction with regards to hospital care and quality of interaction with staff (van Os et al., 2002). In SAFIR and SMARAGD, 20% and 34% of the patients, respectively, were being treated for the first time. The expectations in these patients may have been higher than the expectations of the patients who had received previous antipsychotic therapy. The use of the 2-COM, which facilitates structured dialogue centered on the management of the individual patient, in conjunction with treatment in these individuals may help to reassure the patient that treatment is effective and promote dialogue when it is not. However it is important to highlight that the use of the 2-COM questionnaire may raise false expectations in the patient by allowing him or her to raise issues that the treating physician cannot resolve (van Os et al., 2002).

In both SAFIR and SMARAGD, the investigators anticipated a higher mean number of needs compared to patients at each visit. It was not reported how long the investigator had known the patient before the study; the degree of investigator bias in the analyses performed at Visit 1 cannot be ascertained. Use of the 2-COM questionnaire, extending each patient visit by approximately 13 minutes (van Os et al., 2002), provided the investigator with a better understanding of the patient, as shown by an increase in the concordance of responses at the second and third study visits.

The 2-COM may not detect all needs of the patient but it helps to determine key points regarding therapy (patient satisfaction and unwanted side effects such as weight gain, sedation and fatigue), socio-economic problems (family problems, financial difficulties, housing problems) and co-morbid conditions (for example substance abuse). Van Os et al. reported that the 2-COM questionnaire improved patient-physician communication as mirrored by a greater likelihood of a management change during the period following the 2-COM intervention, especially in patients with higher levels of reported needs (van Os et al., 2004).

Limitations of SAFIR and SMARAGD included the lack of a control arm. The answers at Visits 2 and 3 may have been biased by the knowledge acquired at Visit 1, leading to a higher concordance between the patient and the treating physician. The patient may have given answers that were judged to please the investigator and the investigator's answers may have been influenced by previous knowledge of the patient's expectations. The population in these studies may not be representative since only patients who agreed to answer the 2-COM questionnaire were included (Eisen et al., 2000). Patients with less perception of their illness or with a negative attitude towards their illness may be less likely to agree to participate in a research study.

The significant differences between patient and physician in the perception of the patient needs indicate that physician-patient communication may not always be optimal. This suggests that further information and education campaigns could be required to improve communication between patient and physician. A better communication between patient and physician could improve clinical management and adherence to therapy, which in turn, could result in reduction in economic costs (fewer hospitalizations, fewer days off work due to sickness) and improvement in the patient's quality of life. The systematic and long term use of the 2-COM questionnaire should be considered as a tool to improve communication between treating physician and patient, thereby improving therapy results.

RÉSUMÉ

La communication entre les patients psychotiques et les professionnels de santé est essentielle pour optimiser les soins cliniques et la gestion de la maladie de ces patients. Deux études observationnelles ont été conçues pour évaluer les résultats du traitement par le fumarate de quétiapine (Seroquel®) en association avec le questionnaire 2-COM (« Two-Way Communication »). L'objectif de ces études était d'étudier la perception de l'effet du traitement par le fumarate de quétiapine par les patients atteints de troubles bipolaires ou de schizophrénie et leur médecin traitant. Les résultats du questionnaire 2-COM ont montré que, les investigateurs ont évalué un nombre moyen de besoins plus élevé que les patients eux-mêmes, mais ce nombre a diminué au cours de l'étude. Une augmentation significative du nombre de concordances entre les patients et les investigateurs a également été observée au fil du temps. L'amélioration de la communication entre le patient et le médecin était associée à une amélioration de la gravité de la maladie, évaluée en utilisant l'échelle CGI (« Clinical Global Impression »).

SAMENVATTING

In het bereiken van een optimale zorg en ziektebeheer van psychotische patiënten, speelt de communicatie tussen de patiënt en de gezondheidsverlener een cruciale rol. Twee observationele studies werden ontwikkeld om de resultaten te evalueren van een behandeling met quetiapine fumarate (Seroquel®) en het gelijktijdig gebruik van de "Two-way Communication" (2-COM) vragenlijst. Het objectief van deze 2 studies was een beter inzicht te krijgen in de perceptie van het behandelingseffect met quetiapine fumarate, en dit zowel bij patiënten met schizofrenie en bipolaire manie als bij hun behandelende arts. De resultaten van deze 2-COM vragenlijst toonden aan dat, tijdens elke visite, de arts een gemiddeld groter aantal noden aangaf dan de patiënt zelf. Het gemiddeld aantal noden, zowel door de arts als door de patiënt aangegeven, daalde van het eerste naar het derde studievizite toe. Over het verloop van de studie werd er tevens een significante stijging genoteerd in het aantal overeenkomsten tussen de patiënt en de arts. Een verbeterde communicatie tussen de patiënt en de behandelende arts ging gepaard met een verbetering in de ernst van de aandoening, geëvalueerd aan de hand van de "Clinical Global Impression" schaal.

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