Traitement des patients schizophrènes et bipolaires par le médecin généraliste: Une étude naturaliste de cohorte évaluant les stratégies de traitement en médecine générale

TREATMENT OF SCHIZOPHRENIA OR BIPOLAR PATIENTS BY PRIMARY-CARE PHYSICIANS: A NATURALISTIC COHORT STUDY TO ASSESS TREATMENT STRATEGIES IN GENERAL PRACTICE

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BACKGROUND: THE MAIN OBJECTIVE OF THIS NON-INTERVENTIONAL STUDY IS TO EXAMINE THE ROLE OF GENERAL PRACTITIONERS (GPS) IN THE ASSESSMENT AND MANAGEMENT OF PATIENTS WITH SCHIZOPHRENIA AND BIPOLAR DISEASE. PARTICULARLY, TO INVESTIGATE THE EFFECTIVENESS OF ATYPICAL ANTIPSYCHOTICS (AAPS) AS DEFINED BY THE THREE DOMAINS OF PATIENT FUNCTIONING, EFFICACY AND TOLERABILITY IN A FAMILY PRACTICE SETTING.

METHODS: BETWEEN 2007–2008, 252 PATIENTS WERE ENROLLED IN FAMILY PRACTICES IN BELGIUM. INCLUSION CRITERIA WERE PATIENTS 18–65 YEARS OLD, WILLING AND ABLE TO PARTICIPATE, DIAGNOSED WITH SCHIZOPHRENIA OR BIPOLAR DISORDER, CURRENTLY IN A MANIC EPISODE AND FOR WHOM THE GP DECIDED TO PRESCRIBE AN AAP. PATIENT DEMOGRAPHICS, SELECTION CRITERIA, PSYCHIATRIC AND MEDICAL HISTORY AND CONDITION WERE ASSESSED AT VISIT 1. NAME AND DOSE OF AAP, THE QUALITY-OF-LIFE (QOL) QUESTIONNAIRE Q-LES-Q-16, THE SHEEHAN DISABILITY SCALE (SDS) FOR PATIENT WELL-BEING, THE CLINICAL GLOBAL IMPRESSION (CGI) AND PATIENT GLOBAL IMPRESSION OF CHANGE (PGIC) SCORES FOR CLINICAL EFFICACY AND TOLERABILITY WERE ASSESSED AT VISIT 1 (DAY 0), VISIT 2 (WEEK 4) AND VISIT 3 (WEEK 8).

RESULTS: A TOTAL MEAN CHANGE OF 25 WAS OBSERVED IN THE Q-LES-Q RESULTS. THE SDS TOTAL SCORE DECREASED SUBSTANTIALLY WITH A MEAN CHANGE OF -9. NUMBER OF DAYS LOST AND THE NUMBER OF UNPRODUCTIVE DAYS, AT WORK OR SCHOOL DECREASED WITH A MEAN CHANGE OF -2 AND -2. CGI-S SCORES DECREASED BY A MEAN -2 AND THE CGI-I AND PGIC SCORES ALSO DECREASED.

CONCLUSION: THIS STUDY (NCT00543088) HAS SHOWN THAT PRIMARY CARE PHYSICIANS CAN TREAT SCHIZOPHRENIC OR BIPOLAR PATIENTS EFFECTIVELY WITHOUT HOSPITALIZATION.

Key-words: Schizophrenia, Bipolar Disorder, antipsychotic agents, family practice, quality of life

BACKGROUND

The World Health Organization (WHO) estimates that 26.3 million suffer from schizophrenia worldwide and approximately 29.5 million people have bipolar disease (WHO 2008). An important proportion of these patients are initially diagnosed and referred for psychiatric assessment by GPs (Blashki et al. 2004; Lewin et al. 1998). Self-referral is the cornerstone of entry into medical care. Primary care for mental disorders is affordable and further investment could benefit many patients experiencing extreme suffering, disability and financial loss. However, poor judgment is a key feature of bipolar disease and, in mania or hypomania, seeking help is often delayed because the patient thinks they have many very important tasks to accomplish first.

Hypomania can cause huge financial losses, ruin family life and even lead to suicide. Acute mania is a medical emergency. GPs are often reluctant to treat these patients, because they think they cannot treat the condition or because they need moral support from a psychiatrist to care for such patients. Atypical

antipsychotic (AAPs) drugs are the cornerstone of treatment for psychotic disorders, such as bipolar disorder and schizophrenia, due to their efficacy and side-effect profile Brecher et al. 2007; Ohlsen et al. 2004; Lieberman et al. 2005). Psychiatry generally lacks laboratory or other biological measurements to help assess the presence or severity of illness. Mental health practitioners have developed rating scales to define mental illness more objectively and to standardise the assessment.

We report here the results of the SERENITY study (Clinical-Trials.gov Identifier: NCT00543088), a prospective, multicentre, non-interventional study designed to evaluate the effectiveness of GP-based management of antipsychotic treatment in Belgium of patients presenting with schizophrenia or the manic phase of bipolar disorder. Three major domains have been reported as defining clinical effectiveness: patient functioning, which includes quality-of-life (QoL) and well-being, efficacy, and tolerability, which is linked with the treatment's safety (Nasrallah et al. 2005; Naber et al. 2004).

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METHODS

STUDY DESIGN

The inclusion criteria were: patients willing and able to sign the informed consent form and comply with the study requirements; male or female aged between 18–65 years; diagnosed with schizophrenia or bipolar disorder (currently in a manic phase); patients for whom the GP decided to prescribe atypical antipsychotics (AAPs) in accordance with the Summary of Product Characteristics (SmPC) and current medical practice. Excluded patients included those treated with AAPs during the three months prior to Visit-I, pregnant or lactating women or women of childbearing potential not using a medically reliable method of contraception as stated in the SmPC, and patients with a known intolerance or hypersensitivity to AAPs or other components of the medication.

The primary objective of this study was to evaluate the effect of AAP treatment on QoL, as assessed by the Q-LES-Q-16, a patient's self-completed questionnaire. The secondary objectives were to evaluate the clinical efficacy and tolerability of the prescribed AAPs by using the Clinical Global Impression scores for Improvement (CGI-I) and Severity (CGI-S) and the Patient Global Impression of Change (PGIC) scores; the well-being of the patients was also assessed by the Sheehan Disability Scale (SDS). The PGIC, Q-LES-Q-16 and SDS questionnaires were completed by the patient and the CGI was completed by the GP. This allowed data to be collected on both the patient's and the GP's opinion of the general clinical improvement of the patient during AAP treatment. Completion of these questionnaires took approximately ten minutes. Apart from completing these questionnaires, no additional action was required from the patients.

The patients were followed for 8 ± 2 weeks, with three visits planned, reflecting common medical practice in Belgium. At Visit-I (enrolment), informed consent was obtained and demographic and baseline data (age, gender, psychiatric medical history, current medical condition, additional psychotropic medication) were recorded. At Visit-2 (4 ± 2 weeks) and Visit-3 (8 ± 2 weeks), the CGI-I and PGIC data were collected. At each visit, the Q-LES-Q-I6, SDS, and CGI-S questionnaires, and the prescribed dose of AAPs and additional psychotropic drugs were also collected. Other medication considered necessary for the patient's safety and well-being during and after the study was given at the GP's discretion and fell within current practice.

To ensure that study procedures conformed across all investigator sites, the protocol, case report form and safety reporting were reviewed by an AstraZeneca representative with the investigator and their personnel responsible for the conduct of the study at the investigator site. The study protocol was approved by the Ethics Committee of the University Hospital of Liège.

MEASUREMENT OF OUTCOMES

The Q-LES-Q-16 is a patient assessment of physical health, feelings, leisure activities, social relationships, school, work and household activities. It is a short version of a subset of the 93 questions in the complete Q-LES-Q questionnaire, consisting of the 16 items from the 'General Activities' section. These 16 items cover domains related to functioning and well-being, and has good psychometric qualities in patients with severe mental illness and each item consists of five points ranging from 'not satisfied at all' to 'very satisfied' (Ritsner et al. 2005).

The SDS is a self-rated visual analogue scale comprising five items that measure the extent to which a patient is impaired by panic, anxiety, phobic or depressive symptoms. It evaluates the number of unproductive or underproductive days in three domains: work and school, social life and leisure, and home responsibilities (Leon et al. 1997).

The PGIC is a patient-reported periodic assessment of the change in their condition. It is a one-item scale that assesses treatment response in psychiatric patients.

The CGI is a two-item scale that also assesses treatment response in psychiatric patients. The rating is usually performed by the patient's GP or a trained rater who assesses the severity of illness, clinical progress and therapeutic efficacy (Nasrallah et al. 2005; Naber et al. 2004).

DATA ANALYSIS

The primary variable was the patient-reported outcome Q-LES-Q-16 score, which measured QoL at Visits-1,-2 and -3. The secondary efficacy variables were the SDS scores, which evaluated the well-being of the patients, and the PGIC and CGI scores, which evaluated treatment efficacy and tolerability at Visits-2 and -3.

The Q-LES-Q summary score was based on the total sum score of the first 14 items. For ease of interpretation, this scale was transformed to a scale with a maximum of 100 and a higher summary score indicated a better patient condition. Both values and changes from baseline were calculated. The Q-Les-Q effect size was calculated to determine the minimally clinically interesting population differences. Two operations of the effect size were calculated: (i) the mean change from baseline divided by the baseline standard deviation (STD) and (ii) the mean change from baseline divided by the STD of the differences. These effect sizes were interpreted according to the criteria given by Cohen (1988): an effect size of 0.2 was considered a small effect, of 0.5 was a moderate effect and of 0.8 was a large effect.

By summing the three domains of the SDS, the total impairment was calculated from 0 (unimpaired) to 30 (highly impaired). If one or more of the three subscores were missing (including work/school) then the total score was considered missing. A rating of >5 for any of the SDS domains was considered significant functional impairment and scored 1; otherwise the score was 2. When one or two of the three domain scores were missing and the non-missing domain scores have a rating ≤ 5 , then

the SDS-Clinically significant improvement score was considered missing and scored 0.

The PGIC is a one-line seven-point scale (I = 'very much improved', 7='very much worse').

The CGI-S assesses the severity of illness during the previous week, using a one item question scored from I = `Normal' to 7 = `extremely ill'. The CGI-I assesses improvement since the initiation of the current treatment, using a one item question scored from I ('very much improved') to 7 ('very much worse').

The sample size was calculated by anticipating a dropout rate of 40%; dropping-out was defined as not completing any assessments at Visit-3. A target sample size of 150 would allow for statistically detecting a small to moderate effect size (two-sided t-test: $\alpha = 0.05; \, \rho = 0.5, \, 1 - \beta = 0.90)$ (Cohen 1988). Thus, recruitment of 250 patients was needed so that 150 patients would complete the study and the patient's QoL improvement in routine clinical practice could be accurately estimated.

The Safety population consisted of all patients enrolled in the study who received at least one dose of study medication (prescription). The Per Protocol Population (PPP) set consisted of all patients with valid Q-LES-Q scores at visits-I and -3, after applying windowing conventions, and those who had no serious protocol violations.

Descriptive statistics were calculated, including 95% confidence intervals (Cls). For all continuous efficacy variables, these intervals implied an inferential test (two sided, α =0.05).

RESULTS

PATIENT DEMOGRAPHICS

Between 2007 and 2008, 252 patients were enrolled in 66 study centres in Belgium and included in the safety population analysis. The study was completed by 226 patients with 223 included in the PPP. 51% of patients (n=129) were female and the mean age was 44 \pm 12 (\pm STD) years. 36% of patients were suffering from schizophrenia (n=90) and 64% (n=158) were diagnosed with bipolar disorder and currently in a manic episode; only one person (0.4%) had both disorders. The mean duration of psychiatric disorder was 11 \pm 9 years. Table 1 shows the concomitant psychotropic medication and AAP use at each visit.

IMPACT ON PATIENTS' FUNCTIONING

The Q-LES-Q scores increased significantly throughout the study, indicating an improvement in the patients' QoL (Table 2). The Q-LES-Q effect sizes demonstrated a moderate-to-large effect at Visit-2 and very large effects at Visit-3.

Table I. Use of concomitant psychotropic and AAP medication during the study

| Medication used | Visit-I (Baseline) | Visit-2 (Week 4±2) | Visit-3 (Week 8±2) |
|--|-----------------------|--------------------------|--------------------------|
| Antipsychotics | 3 | 4 | 3 |
| Antidepressants | 48 | 50 | 48 |
| Benzodiazepine | 60 | 62 | 61 |
| Mood stabilizer | 5 | 4 | 4 |
| Other | 3 | 4 | 5 |
| Combinations | | | |
| Mood stabilizer + Benzodiazepine | 4 | 4 | 4 |
| Benzodiazepine + Antidepressants | 51 | 42 | 37 |
| Benzodiazepine + Antipsychotics | 2 | 2 | 2 |
| Antidepressants + Antipsychotics | 0 | I | ı |
| Other + Mood stabilizer | 1 | - 1 | 1 |
| Other + Benzodiazepine | 4 | 3 | 1 |
| Other + Antidepressants | 2 | 2 | 2 |
| Mood stabilizer + benzodiazepine + Antidepressants | 3 | 3 | 3 |
| Benzodiazepine + Antidepressants + Antipsychotics | 4 | 2 | ı |
| Other + benzodiazepine + Antidepressants | 2 | 2 | 2 |
| Other + Mood stabilizer + Antipsychotics | I | 1 | ı |
| No concomitant psychotropic medication | 59 | 54 | 53 |
| Missing not due to dropout | 0 | 3 | 6 |
| Missing due to dropout | 0 | 8 | 17 |
| Number of dropouts | 0 | 12 | 26 * |
| AAP Prescription | | | |
| Quetiapine | 217 | 206 | 197 |
| Aripiprazole | 5 | 5 | 7 |
| Clozapine + clorazepine | 0 | 0 | 0 |
| Risperidone | 9 | 9 | 8 |
| Risperidone (long-acting injection) | 0 | 0 | ı |
| Olanzapine | 18 | 16 | 12 |
| Risperidone (long-acting injection) + quetiapine | ı | I | 0 |
| Risperidone + quetiapine | 1 | 0 | 0 |
| Aripiprazole + quetiapine | 1 | 2 | 2 |
| No atypical antipsychotic medication | 0 | 2 | 7 |
| Missing not due to dropout | 0 | 3 | 4 |
| Missing due to dropout | 0 | 8 | 14 |
| Number of dropouts | 0 | 12 | 26 * |

^{*} The number of patients who dropped out at Visit 3 but did not drop out at Visit 2 is 14. The number shown is the total number of dropouts at visit 3.

Table 2. The Q-LES-Q summary scores and effect size

(Per Protocol Population, n = 223)

| | Visit I Visit 2 | | | Visit 3 | | | |
|---------------|-----------------|---------------|----------------------|-------------|---------------|----------------------|-------------|
| | (Baseline) | (Week 4 ±2) | | (Week8 ±2) | | | |
| Parameter | Actual values | Actual values | Change from baseline | Effect Size | Actual values | Change from baseline | Effect Size |
| N analyzed | 223 | 221 | 221 | - | 223 | 223 | - |
| N missing | 0 | 2 | 2 | · - | 0 | 0 | - |
| Mean | 36.32 | 51. 18 | 15.07 | - | 60.95 | 24.62 | - |
| STD | 20.13 | 19.36 | 17. 93 | - | 17.43 | 22.15 | - |
| 95% CI | 33.67–38.98 | 48.61–53.75 | 12.69–17.45 | - | 58.65–63.25 | 21.70–27.55 | - |
| Effect Size I | | | | 0.75 | | | 1.21 |
| Effect Size 2 | | | | 0.83 | | | 1.12 |

Analyzing the PPP subset data for patients with schizophrenia revealed that, of the 79 Q-LES-Q scores analyzed, the mean summary score at Visit-I was 35 \pm 17 (95%CI 31–38), and the mean change from baseline was a statistically significant 27 \pm 22. At Visit-3, the Q-LES-Q effect size was 1.60 and the effect size 2 was 1.24 for the schizophrenia subgroup.

The SDS total scores decreased substantially during the study (Table 3). These scores are statistically significant and sufficiently substantial to assume that the patients became less functionally impaired as the study progressed. The schizophrenia subset of patients recorded a mean SDS total score of 21 ± 7 at Visit-1, which changed significantly by -12 ± 7 at Visit-3. The bipolar subset had a mean total score of 20 ± 8 , which changed significantly from baseline at Visit3 by -8 ± 9 .

Each of the SDS scores for well-being at work or school, in social life and leisure, and in family life significantly decreased at Visits-2 and -3 (Table 3). In general, patients with a 'Moderate' score or higher at baseline tended to score lower at follow-up visits, indicating an improvement, and patients scoring 'Mild' or 'Not at all' scored the same or slightly higher (indicating deterioration) at subsequent visits.

The SDS scores for the number of days lost at work or school decreased significantly during the study from a mean of 3 \pm 3 at baseline to 2 \pm 3 and 1 \pm 3 at Visits 2 and 3. SDS scores for the number of unproductive days at work or school all decreased significantly from a mean of 3 \pm 3 days at baseline to 2 \pm 3 and 1 \pm 2 days at Visit-2 and -3.

In the schizophrenia data subset, a mean SDS score of 6 ± 3 (6–7) was recorded for the disruption of family life and impairment regarding home responsibilities; this score was significantly reduced by 52% to 3 ± 2 (3–4) at Visit-3. For the same assessment, the bipolar data subset scored a mean 7 ± 3 (6–7) with a mean significant reduction of 43% to 4 ± 3 (3–4) after Visit3.

AAP TREATMENT EFFICACY AND TOLERABILITY

The CGI-S scores decreased significantly during the study (Figure I). Both the patients with schizophrenia and the bipolar patients scored a mean $5 \pm I$ at baseline with a mean, significant change of $-2 \pm I$ at Visit-3.

The CGI-I score decreased from 3 ± 1 at Visit-2 to 2 ± 1 at Visit-3 and the PGIC scores decreased from 3 ± 1 at Visit-2 to 2 ± 1 at Visit-3. The schizophrenia patients scored 3 ± 1 with the CGI-I at Visit-2 and 2 ± 1 at Visit-3; bipolar patients scored 3 ± 1 at Visit-1 and 2 ± 1 at Visit-3. Furthermore, the majority of both schizophrenia and bipolar subsets showed improvement in their conditions after the second visit and even more so by the third visit (Figure 1). This can also be seen in the results on functional impairment (Table 3).

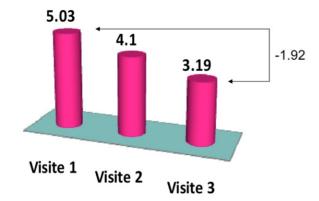


Figure 1. Graph showing CGI Improvement Scale of Schizophrenia and Bipolar Disease in manic phase data subsets.

Per Protocol Population, Schizophrenia N=79, Bipolar Disease N=140

Table 3. Sheehan Disability Scale (SDS) scores for well-being at work or school, in social life and leisure and in family life.

(Per Protocol Population, n= 223)

| | - Parameter | Visit I (Baseline) | | sit 2 k 4 ±2) | Visit 3 (Week 8 ±2) | |
|---|----------------|-----------------------|---------------|----------------------|------------------------|----------------------|
| | | Actual values | Actual values | Change from baseline | Actual values | Change from baseline |
| Total Score Summary | N analyzed | 204 | 198 | 197 | 142 | 142 |
| | N missing | 19 | 25 | 26 | 81 | 81 |
| | Mean | 20.18 | 13.97 | -6.29 | 10.45 | -9.26 |
| | STD | 7.43 | 7.22 | 7.24 | 7.44 | 8.56 |
| | 95% CI | 19.16 – 21.21 | 12.96 – 14.99 | -7.31 – -5.28 | 9.22 – 11.69 | -10.68 – -7.84 |
| Well-being at work or school | N analyzed | 204 | 202 | 201 | 206 | 201 |
| | N missing | 19 | 21 | 22 | 17 | 22 |
| | Mean | 6.89 | 4.98 | -1.93 | 3.82 | -3.11 |
| | STD | 2.74 | 2.56 | 2.57 | 2.64 | 3.04 |
| | 95% CI | 6.51 – 7.27 | 4.63 – 5.33 | -2.28 — -I.57 | 3.46 – 4.18 | -3.53 — -2.69 |
| Well-being in social life and leisure | N analyzed | 223 | 220 | 220 | 223 | 223 |
| | N missing | 0 | 3 | 3 | 0 | 0 |
| | Mean | 6.57 | 4.40 | -2.20 | 3.37 | -3.20 |
| | STD | 2.80 | 2.54 | 2.63 | 2.52 | 2.89 |
| | 95% CI | 6.20 – 6.94 | 4.07 – 4.74 | -2.55 – -1.86 | 3.04 – 3.71 | -3.58 – -2.82 |
| Well-being in family life | N analyzed | 223 | 220 | 220 | 223 | 223 |
| | N missing | 0 | 3 | 3 | 0 | 0 |
| | Mean | 6.50 | 4.62 | -1.92 | 3.48 | -3.02 |
| | STD | 2.79 | 2.55 | 2.95 | 2.55 | 3.16 |
| | 95% CI | 6.13 - 6.87 | 4.28 - 4.96 | -2.321.53 | 3.15 - 3.82 | -3.432.60 |

Schizophrenia patients were rated as 'much improved' on the PGIC scale at Visit-3 (2 \pm 1); bipolar patients were also rated as 'much improved' (2 \pm 1).

DISCUSSION

PRINCIPAL FINDINGS

In this study, the patients' QoL scores improved considerably between baseline and the two follow-up visits, particularly in patients with schizophrenia. The SDS scores indicated an improvement of the patients' general well-being. Patients lost fewer days at work or school and also had fewer days which were unproductive at work or school throughout the study. The significantly decreased CGI-S, CGI-I and PGIC scores indicated that the patients became less severely ill and there was

clinical improvement. Thus, the GP's prescription of AAPs for the treatment of the manic phase of bipolar disorder and schizophrenia have been effective in improving the patient's feeling of well-being and functional ability, including a significant reduction in the number of days lost at either school or work. Primary care for mental health generates good health outcomes, is affordable and cost effective. AAP treatment enhances the patient's competence and autonomy.

STRENGTHS AND WEAKNESSES OF THE STUDY

It is probable that the improvements reported here were responsible for the considerably smaller number of dropouts from the study than were expected. The sample size was calculated assuming 100 patients would dropout, whereas only 24 were withdrawn (non-adherence [N=14], adverse events [N=6], lack of efficacy [N=3] and withdrew consent [N=1]). Further information regarding the adverse events was not collected.

Due to the nature of non-interventional, observational studies within standard medical practice (such as the lack of a control group), a strong inference on a direct causal relationship between the administration of AAPs and patient status is not warranted. However, the treatment described in this paper in the context of family practices does indeed seem to have a positive effect.

by the differing health systems being studied. While one study in the Netherlands reported that psychiatric patients contact their GPs more often than other types of patients, another study in Canada commented that "GPs prove to be an underutilized resource" for treating patients with mental disorders (Oud et al. 2010; Fleury et al. 2010). Our results would reinforce the recommendations of Fleury et al (2010) that interactions with GPs should be improved particularly in relation to patient follow-up.

COMPARISON WITH EXISTING LITERATURE

Very few studies have examined QoL and the management of mental health disorders by GPs and this is further complicated

CONCLUSIONS

This study has shown that, with AAP medication in a family practice setting, it is possible to manage patients suffering from bipolar disorder or schizophrenia to such a degree that hospitalization is no longer required and the patients can once again function in society, being productive at work or school and taking on more responsibility within the home.

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COMPETING INTERESTS

Prof. William Pitchot received an unrestricted grant from AstraZeneca. He also has served as a speaker for GSK, BMS, AstraZeneca, Eli Lilly, and Lundbeck. He is a member of the advisory boards of AstraZeneca, Eli Lilly, BMS, and Servier. Dr Moeremans declares no conflicts of interest. Annelies Vankeirsbilck and Tineke Vanlerberghe are both employees of AstraZeneca.

RÉSUMÉ

Objectifs : L'objectif principal de cette etude non-interventionnelle est d'examiner le rôle des médecins généralistes dans l'évaluation et la prise en charge des patients souffrant de schizophrénie et de trouble bipolaire. En particulier, investiguer l'efficience des antipsychotiques atypiques au niveau du fonctionnement du patient, de l'efficacité et de la tolérance en médecine générale.

Méthode : Entre 2007 et 2008, 252 patients ont été inclus en médecine générale en Belgique. Les critères d'inclusion étaient les suivants: patients âges de 18 à 65 ans d'accord de participer à l'étude, répondant aux critères diagnostiques de schizophrénie ou

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Doelstellingen: Het hoofdoel van deze niet-interventionnelle studie is de rol van de huisartsen in de evaluatie te onderzoeken en de overname van de patiënten die aan schizofrenie en bipolaire ziekte lijden . Vooral, de efficiëntie van atypisch antipsychotiques op het niveau van de werking van patiënt, van de doeltreffendheid en de tolerantie bij huisartsen te evaluëren.

Methode: Tussen 2007 en 2008, 252 patiënten werden bij Belgische huisartsen in de studie ingesloten. De inclusie criteriazijn de volgende: leeftijd tussen 18 en 65 jaar, patiënte van overeenkomst om aan de studie deel te nemen, met een diagnostische

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de trouble bipolaire, en phase maniaque au moment de l'inclusion, et pour lesquels le médecin généraliste décide de prescrire un antipsychotique atypique. Les caractéristiques démographiques, les critères de selection, les antécédents psychiatriques et médicaux étaient évalués à la visite I. Le nom et la dose d'antipsychotique atypique, l'échelle de qualité de vie (QoL) Q-LES-Q-16, l'échelle d'incapacité de Sheehan (SDS), les scores d'Impression Clinique Globale (CGI) et de Perception Globale de Changement par le Patient (PGIC) pour l'efficacité Clinique et la tolérance étaient évalués à la visite I (jour 0), la visite 2 (semaine 4) et la visite 3 (semaine 8).

Résultats : Un changement moyen de 25 sur l'échelle Q-LES-Q a été observé. Le score total à l'échelle de Sheehan a diminué sensiblement avec un changement moyen de 9. Le nombre de jours d'absence à l'école et au travail a diminué. Les scores à l'échelle CGI-S ont diminué en moyenne de 2 et les scores CGI-I et PGIC ont également diminué.

Conclusion : Cette étude montre que la schizophrénie et le trouble bipolaire peuvent parfois être traités efficacement dans le cadre de la médecine générale.

MOTS-CLÉS : Schizophrénie – Trouble bipolaire – Antipsychotiques – Médecine générale – Qualité de vie

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criteria van schizofrenie of bipolaire ziekte, in maniakale fase op het moment van het inclusie, en waarvoor de huisarts besluit om een atypisch antipsychotique voor te schrijven. De demografische kenmerken, de selectie criteria, de psychiatrische en geneeskundige antecedenten werden aan het bezoek I geëvalueerd. De naam en de dosis van atypisch antipsychotique, de levenskwaliteit schaal (QoL) Q-LES-Q-16, de onvermogen van Sheehan schaal (SDS), de resultaten van Klinische Globale Indruk (CGI) en van de Patiënt Globale Veranderingswaarneming (PGIC) voor de Klinische doeltreffendheid en de tolerantie werden aan het bezoek I (dag 0), bezoek 2 (week 4) en bezoek 3 (week 8) geëvalueerd.

Resultaten: Een gemiddelde verandering van 25 op de schaal Q-LES-Q werd geobserveerde. De totale score op de schaal van Sheehan werd merkbaar verminderd met een gemiddelde verandering van 9. Het aantal dagen van afwezigheid op school en het werk werd verminderd. De scoren op de schaal CGI-S werden gemiddeld met 2 verminderd en de standen CGI-I en PGIC hebben eveneens verminderd.

Conclusie: Deze studie toont aan dat de schizofrenie en de bipolaire ziekte kunnen soms doetreffend bij huisartsen behandeld worden

SLEUTELWOORDEN: Schizofrenie – bipolaire ziekte – Antipsychotiques – huisartsen – Levenskwaliteit

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