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Observational Study of the Clinical Management of Bipolar Disorder in China

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NIS REPORT SYNOPSIS

Observational Study of the Clinical Management of Bipolar Disorder in China

Study sites

The subjects of this study were recruited from 7 hospitals in China, including mentalhospitals and general hospitals with psychiatric departments. Appendix A contains a list of the participating centers and the principal investigators.

Publications

Xin Yu. Patterns Of Disease And Therapy In Chinese Bipolar Disorder: An Interim Analysis Of Retrospective Data From A Large Ambispective Study In China (Cast-Bd). Poster in the XVI World Congress of Psychiatry.Poster Number: NR3-020.

Study dates

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Objectives

Primary objective

To describe clinical management and clinical outcomes related to Bipolar Disorder (BD) in real-life settings in China.

Study design

This was a multicentre, observational, ambispective study of patients diagnosed with BD type I or II with at least one mood event in the 3 to 12 months prior to the study started.

This study included a retrospective and a prospective phase:

- The retrospective phase for each patient started from 12 months prior to the study started, and ended when the patient signed the informed consent form.
- The prospective phase started when the patient signed the informed consent form, and ended in the 9th month after enrolment. In the prospective phase, the required information was recorded and the questionnaires were completed in the 1st month, 3rd

month, 6th month and 9th month after the patient signed the informed consent form. The psychiatrist scheduled visits according to real-life clinical practice.

No interventions, extra procedures, or extra visits were required for the purpose of the study.

To ensure that the patient population was representative of the whole situation of BD in China, different types of centers were selected to participate in the study, included psychiatric hospitals and general hospitals in different regions. The number of patients enrolled in each hospital was no morethan 150.

Patients participating in the study had to fulfill the following inclusion criteria:

1. Provided a signed informed consent form
2. Age ≥18 years
3. Diagnosed with BD-I or II (according to DSM-IV TR)
4. Experienced at least one mood event (depression, mania, hypomania or mixed) according to DSM-IV TR definition betweenthe 12 months before the beginning of the study and 3 months before study.

Patients were excluded from the study when they:

1. Were unable to complete PROs questionnaires
2. Were participating in an interventional clinical study during the past year

Patients could withdraw from the study at any time, and were asked to provide a reason for the withdrawal.

Target patient population and sample size

Of555 patients screened fromthe 7 sites, 35 patients did not meet all inclusion criteria and 520 patients from 7 sites were enrolled.

Criteria for evaluation

Criteria for evaluation included patient demographics, medical history, disease characteristics, treatment information, health-care resources consumption and clinical outcomes (recurrence,

suicide attempt and patient-reported outcomes). The patient-reported outcomes (PRO) questionnaires, including MDQ and QIDS, were self-reported by the subjects.

Statistical methods

All subjects who met inclusion/exclusion criteria and had data of retrospective phase were included in Full Analysis Set (FAS) of this study. The FAS was the major population for analysis.

A descriptive analysis approach was used for continuous variables (n, mean, median, standard deviation [SD], minimum or maximum) and categorical variables (n, frequency, and percentage).

Results

Patient demographics and co-morbidities history

A total of 520 patients were enrolled, including 252 (48.46%) malesand 268 (51.54%)females. There were 398 (76.54%) patients diagnosed as Type I and 122 (23.46%) were Type II.The mean (±SD) of age was 35.65(±13.23) years. The mean (±SD) of education was 13.10(±3.40) years. A total of 221 (42.5%) patients were permanently employed, 69(13.27%) patients were temporarily employed and 230 (44.23%) patients were unemployed. There were 478 (91.92%) patients living accompanied and 36 (6.92%) patients with substance abuse.

Of 520 patients enrolled, 59 (11.35%) patients suffered from co-morbidities that required long-term treatment. The most common diseases were hypertension (3.65%) and hyperlipidemia (1.73%).

Of 520 patients enrolled, 151 (29.04%) patients had family psychiatric history, of which the most common was mood disorder (13.46%), followed by schizophrenia (5.77%).

Patient demographics and characteristics of co-morbidities history were comparable between BD-I patients and BD-II.

Patient baseline disease characteristics

Of 520 patients in FAS, the mean (±SD) patient age for the first symptom associatedwith BD was 30.39(±12.21) years. The majority of patient'sfirst episode were depressive episode (59.04%). The common psychiatric diagnoses before BD were depressive disorder,

schizophrenia and anxiety disorder in BD-I patients, depressive disorder and anxiety disorder in BD-II patients.

Of 520 patients, the mean (±SD) age of the patient at BD diagnosis was 32.28(±12.46) years. It was higher in patients with BD-II than in those with BD-I.

The mean (±SD) disease duration of BD was 6.83(±8.38) years. It was similar between patients with BD-I and BD-II. After being diagnosed as BD, the mean number of subjects who had hospitalized and the mean time of hospitalization in BD-I patients were higher than BD-II patients. The percentage of suicide attempts in BD-II patients was higherthan that in BD-I patients.

Patient clinical outcomes

During the 12-month retrospective phase and 9-month prospective phase, all the 520 patients in FAS had recurrences. There were 1262 times of recurrences during the study and the mean (±SD) time of recurrence was 2.43(±1.63). The most common type of recurrence was depressive recurrence and a total of 372 patients had 579 times of depressive recurrences. 225 patients with recurrences had psychotic symptoms, which occupied for 43.27% of all patients. The percentage of psychotic symptoms in BD-II patients was lower than that inBD-I patients. A total of 297 (57.12%) patients attempted suicide during the study. Incidence of suicide attempt in BD-II patients was much higher than that of BD-I patients.

Patient clinical management

In FAS, a total of 517 (99.42%) patients received psychotropic drugs. Most of patients received combination treatments and 307 (59.04%) patients received three or more medications. The most common prescribed drug was valproic acid (68.08%), followed by lithium (55.77%) and quetiapine (54.62%). The most common types of drugs was traditional mood stabilizers, antipsychotics and antidepressants. BD-II patients received more antidepressants than BD-I patients.

In manic episodes, the most common types of drugs were traditional mood stabilizers, antipsychotics and anxiolytics, while during hypomanic, depressive or mixed episodes, the most common types of drugs were traditional mood stabilizers, antipsychotics and antidepressants.

In FAS, 157 (30.19%) patients received non-drug therapy, the most common types of non-drug therapy was ECT. A total of 123 (23.65%) patients received 199 times of ECT.