Research Protocol for REAP Bipolar Disorder (REAP-BD)

Summary

REAP-BD survey will focus on the prescription patterns on bipolar disorder. Both inpatients and outpatients with bipolar disorder will be enrolled. Data in the form of diagnosis, demographics, daily medications regimen, laboratory checks, side effects, and comorbidities will be collected using internet web-based data key-in system. The participating centers and members will be recruited from 16 countries and regions. These are Bangladesh, China, Hong Kong, India, Indonesia, Japan, Korea, Malaysia, Myanmar, Pakistan, Philippines, Singapore, Sri Lanka, Taiwan, Thailand, and Vietnam.

Each centers and participating members will be asked to key in the data form by web site located in Taipei. It is hoped to collect around 50 cases from each participating centers from 13 countries and areas. In total, 2000-3000 cases will be hopefully collected.

Background

Asian Psychotropic Prescription Study (REAP, http://reap.asia/index.html) is a collaborative consortium conducted by psychiatrists, pharmacologists, epidemiologists, and related researchers in Asia, to survey the differences of prescription pattern of psychotropic drug among Asian countries.

Since 2001, REAP has completed four surveys for patients with schizophrenia, and two surveys on antidepressant usages. In the recently completed REAP-AP4, 15 countries/regions including China, Hong Kong, Japan, Korea, Singapore, Taiwan, India, Malaysia, Thailand, Indonesia, Pakistan, Vietnam, Bangladesh, Sri Lanka and Myanmar participated.

Objectives of the study

Treatment of bipolar disorder mainly depends on pharmacotherapy, supplemented by social and psychological intervention. The major drugs are mood stabilizers and antipsychotics, sometimes combined with anxiolytics and hypnotics. In a few situations, some patients are prescribed with antidepressants.

The aim of REAP-Bipolar Disorder (REAP-BD) is to survey the prescription pattern in bipolar disorder in Asian countries, including mood stabilizers, antipsychotic and other psychotropic drugs, to generate the rate of polypharmacy, the dosage of each class of drug, different proportion of mood stabilizers, rate of first and second generation antipsychotics, and other combined medications. Through the survey of prescription pattern in the treatment of bipolar disorder in Asian countries, a comparison between countries and then a consensus may be reached. REAP-BD results can provide the country's psychiatrists as a reference for the prescription, or the health authorities for policy decision-making.

Inclusion criteria

The method used in this study was similar to that of REAP-AP4.

Since both Diagnostic and Statistical Manual of Mental Disorders (DSM) system and the International Classification of Diseases (ICD) system were used in most countries, the ICD 10th Revision, Clinical Modification (ICD-10-CM) will be used as standard diagnosis system in this study. The Bipolar Chapter Codes range fromF31.0X to F31.9X (Appendix 1).A code of 4 or 5 digit from ICD-10-CM system in type and phase with severity level will be used to reflect the rationale of prescription pattern. An interchange between the DSM-5 and ICD-10-CM systems can be retrieved from https://www.psychiatry.org/psychiatrists/practice/dsm/updates-to-dsm-5/coding-updates.

Participating centers

Participating countries/regional are expected as same in the REAP-AP4 including China, Hong Kong, Japan, Korea, Singapore, Taiwan, India, Malaysia, Thailand, Indonesia, Pakistan, Myanmar and Philippine.

Duration (two month data collection between May and September depending on the readiness of IRB approval)

February and March 2018: Preparatory phase: Sending the protocol and questionnaire to leaders.

End March: Agreement of research protocol and participating centers

April to June; IRB clearance at the survey sites

May to September: Survey for the duration of two month after the clearance of IRB.

October: Data compilation and analysis.

December: Sending out of compiled data to participating members.

January 2019: Presentation at congresses and writing papers.

Patient enrollment

Convenience sampling method will be used to enroll the study subjects. Patient with bipolar disorder currently undergoing pharmacotherapy can join this survey. Participating psychiatrists should judge the patient according to his/her clinical features and status to have an ICD-10-CM Codes from F31.0 to F31.9.

Sampling

1) Patients with the diagnoses of BD will be recruited both from inpatients and outpatient of a center.
2) The suggest number (either inpatients or outpatients) to be collected from each site will be 50 and the maximum number from a country will be 300. In total 2000-3000 cases will hopefully collected.
3) Study duration for two month: From the day to start the survey at each center, e.g., 1st of July to 31st August 2108, all patients with the diagnoses of BD can be enrolled.
4) National coordinator will collaborate with several centers to get the minimum number of patient with BD.

Methodology

An internet web-based platform will be created to collect the basic information

and clinical data, same as REAP –AP 4 survey in 2016. This platform can now provide similar multi-national multi-center large-scale data collection research.

Data to be collected (See separate Data Form)

1. Patient Profiles, including demographics, body weight and height, and blood pressure.
2. Duration of bipolar disorder, type of course, duration of untreated illness (DUI, from the onset until first pharmacotherapy, choose one), financial status, and medication coverage.
3. Specified Diagnosis of Bipolar Disorder, based on ICD 10th Revision, Clinical Modification criteria (ICD10-CM, Appendix 1), to adequately indicate patient's current illness status and severity.

3. Course, duration of current episode.

4. Prescription Drugs: Use the dropdown menu to select the drug in generic name used by the patient. Psychotropic drugs are divided into five classes: mood stabilizer, antipsychotic (including long-acting injection), antidepressant, anxiolytic, and hypnotic. If a drug isnot listed, blank boxes are reserved for key-in the generic name and daily dosage. Concomitant non-psychotropic drugs are also required to collect by key-in.
5. History of electroconvulsive therapy.
6. Adverse event : Movement disorder, Autonomic adverse effects, Endocrinological, disturbance, Metabolic dysfunction, Cardiovascular adverse effect, and others.
7. Physical comorbidity: Myocardial infarction, Congestive heart failure, Peripheral vascular disease, Cerebrovascular disease, Dementia ... etc.
7. Use of addictive substances: including tobacco, alcohol, betel nut, marijuana, ketamine, amphetamines, methamphetamines etc, whether in the current or past.

8 .If available:

Laboratory data: including blood routine, blood sugar, liver function, kidney function, thyroid function, prolactin …..etc. Also the most recent blood concentration of mood stabilizers including lithium, valproic acid and carbamazepine are required to display when available.

Funding

Taiwanese Ministry of Science and Technology and Taipei City Health Bureau support a web design preparation and the data management. REAP Consortium members will collect the data voluntarily.

IRB Approval

IRB approval was granted by the Internal Review Committee of Taipei city Hospital Research Ethics Committee.

Each center are requested to get the IRB approval and the consent from BD patients to use the data for REAP survey.

Usage of the data

Members who contributed to the survey are encouraged to make presentation and write scientific papers based on the results of REAP BD.

REAP MS

After the completion of REAP-BD, it is proposed to undertake drug centered survey on REAP-Mood Stabilizers.

Patients of different categories such as depression, schizophrenia and other diagnoses who are receiving Mood stabilizer will be surveyed.

Appendix 1

http://www.icd10data.com/ICD10CM/Codes/F01-F99/F30-F39/F31-/F31

F31 Bipolar disorder

F31.0 Bipolar disorder, current episode hypomanic

F31.1 Bipolar disorder, current episode manic without psychotic features

F31.10 …… unspecified

F31.11 …… mild

F31.12 …… moderate

F31.13 …… severe

F31.2 Bipolar disorder, current episode manic severe with psychotic features

F31.3 Bipolar disorder, current episode depressed, mild or moderate severity

F31.30 …… unspecified

F31.31 Bipolar disorder, current episode depressed, mild

F31.32 Bipolar disorder, current episode depressed, moderate

F31.4 Bipolar disorder, current episode depressed, severe, without psychotic features

F31.5 Bipolar disorder, current episode depressed, severe, with psychotic features

F31.6 Bipolar disorder, current episode mixed

F31.60 …… unspecified

F31.61 …… mild

F31.62 …… moderate

F31.63 …… severe, without psychotic features

F31.64 …… severe, with psychotic features

F31.7 Bipolar disorder, currently in remission

F31.70 …… most recent episode unspecified

F31.71 Bipolar disorder, in partial remission, most recent episode hypomanic

F31.72 Bipolar disorder, in full remission, most recent episode hypomanic

F31.73 Bipolar disorder, in partial remission, most recent episode manic

F31.74 Bipolar disorder, in full remission, most recent episode manic

F31.75 Bipolar disorder, in partial remission, most recent episode depressed

F31.76 Bipolar disorder, in full remission, most recent episode depressed

F31.77 Bipolar disorder, in partial remission, most recent episode mixed

F31.78 Bipolar disorder, in full remission, most recent episode mixed

F31.8 Other bipolar disorders

F31.81 Bipolar II disorder

F31.89 Other bipolar disorder

F31.9 Bipolar disorder, unspecified