Proposal for REAP MS (Revised on 20180309)

Summary outline of the project

Research on Asia Psychotropic Prescription Pattern on Mood Stabilizers (REAP-MS)

REAP-MS survey will focus on the prescription patterns on mood stabilizers in psychiatric patients. Both inpatients and outpatients with the diagnosis other than 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

Mood stabilizer is a category of psychotropic drugs mainly for treating mood disorders in acute phase or relapse prevention (maintenance therapy). Mood stabilizers include lithium, carbamazepine (oxcarbazepine), valproic acid and lamotrigine and others. While besides in the treatment of bipolar disorders, mood stabilizers sometimes are used in other psychiatric disorders such as schizoaffective disorder, major depression, schizophrenia and many others as adjunct or add-on medications, or even as the monotherapy (primary medication). The aim of REAP-MS is to survey the prescription pattern of mood stabilizers in patient with the diagnosis other than bipolar disorder in Asia, to analyze the distribution of psychiatric diagnoses receiving mood stabilizers and to study the differences in the type of mood stabilizers, targeted symptoms, their doses and plasma level if available. Through the survey of prescription pattern in the treatment of mood stabilizers in Asian countries, a comparison between countries and then a consensus may be reached. REAP-MS 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.

Psychiatric inpatients or outpatients prescribed with lithium, carbamazepine (oxcarbazepine), valproic acid and lamotrigine (or other antiepileptics), and their diagnoses are not bipolar disorder will be enrolled. The ICD 10th Revision, Clinical Modification (ICD-10-CM) will be used as standard diagnosis system in this study.

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 September 2018 and February 2019 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 December; IRB clearance at the survey sites (depends on each site to submit IRB as one protocol (REAP 2018 BD and MS) or separately
September to February 2019: Survey for the duration of two month after the clearance of IRB.
April 2019: Data compilation and analysis.
June 2019: Sending out of data to participating members.
July 2019: Presentation at congresses and writing papers.

Patient enrollment

Convenience sampling method will be used to enroll the study subjects. Patient with diagnosis other than bipolar disorder currently receiving mood stabilizers can join this survey. Participating psychiatrists should judge the patient according to his/her clinical features and status to have an ICD-10-CM Major psychiatric diagnoses.

Sampling

1) Patients with the diagnoses other than bipolar disorder and receiving mood stabilizers 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 December 2018 to 31st January 2109.
4) National coordinator will collaborate with several centers to get the minimum number of patient.

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. Psychiatric diagnoses, duration of untreated illness (DUI, from the onset until first pharmacotherapy, choose one), financial status, and medication coverage.
3. Physical comorbidities and targeted symptom of mood stabilizers.
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 is not 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. Adverse event : including cardiovascular, cognitive, dermatological, endocrinological, gastrointestinal, hematological, immunological, metabolic, nephrogenic, neurological, and sexual adverse event.
6. Use of addictive substances: including tobacco, alcohol, betel nut, marijuana, ketamine, amphetamines, methamphetamines etc, whether in the current or past.
7. 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 MS.