Profile of adverse drug events in depressed inpatients in China and associated risk factors: a retrospective review using the Global Trigger Tool

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Abstract

Objective: The aim of the study was to evaluate the feasibility and potential of the Global Trigger Tool (GTT) for identifying the adverse drug events (ADEs) in patients with depression. Methods: In this study, the trigger items for antidepressants were developed base on the 'Institute for Healthcare Improvement (IHI) GTT for Measuring Adverse Events' . Trigger detection of the medical records was carried out in 200 patients diagnosed with depression in a specialized hospital. Each medical record with the presence of any of the triggers was reviewed by two researchers respectively to determine whether it was an ADE, if so, ADE should be classified in severity, and involved system and primary suspected drug were identified. Logistic regression was performed to investigate risk factors associated with ADEs, and ADE detection rate and positive predictive value (PPV) were calculated to evaluate the sensitivity and specificity of the triggers. Results: Triggers were detected for 162 times in 159 cases (79.5%), and 69 ADEs in 61 patients were identified by record reviewing. the PPV of the trigger tool was 42.59%. 79.7% were classified as category E, and 20.30% category F. ADEs were most likely to involve metabolic system (34.78%), manifested as hypokalemia, pathoglycemia and hypercholesterolemia. venlafaxine was most likely to cause AEs (32.56%), followed by paroxetine (22.09%). Risk factors for ADEs included the number of administrated antidepressants (p=0.008) and the number of concomitant drugs (p=0.014). Conclusion: The GTT is a feasible and effective tool for detecting ADEs of antidepressants for inpatients.

Dear Editors:

We would like to submit the enclosed manuscript entitled *"**Profile of adverse drug events in depressed inpatients in China and associated risk factors: a retrospective review using the Global Trigger Tool**"* , which we wish to be considered for publication in British Journal of Clinical Pharmacology . The work described was original research that has not been published elsewhere and not been submitted simultaneously for publication elsewhere. All authors have contributed to the paper significantly, and all authors are aware of the submission and agree with it.

Antidepressant (AD) is one of the elementary treatments for depression. The number of people using ADs worldwide has increasing significantly in recent years. The increasing use of ADs has aroused concerns on the adverse drug events (ADEs) monitoring in clinical practice.

Traditional methods to detect ADEs are mainly passive monitoring by spontaneous reporting, which accounting for only 10-20% of the total ADEs. The Global Trigger Tool (GTT) developed by the Institute for Healthcare Improvement (IHI) is a retrospective review of a random sample of inpatient hospital records

using "trigger" to identify possible ADEs, and appears to increase the rate of ADE detection 50-fold from traditional reporting methods.

Different triggers have been established for different clinical department. Nevertheless, no trigger was specifically designed for a certain disease previously. In this study, trigger items suitable for depression were established for active monitoring of ADEs in inpatients, and the feasibility and potential of the Global Trigger Tool (GTT) were evaluated.

To our knowledge, this was the first study to investigate ADEs of medicines for a certain disease using global trigger tools. It was found that GTT was an effective method for identifying ADEs in depressed inpatient with a relatively high positive predictive value (42.59%), and the incidence of adverse reactions detected by GTT was much higher than that of spontaneous report. Constipation, hypokalemia, tachycardia and hypertension were the most common adverse reactions in hospitalized patients taking antidepressants. Number of ADs and concomitant medications were shown to be the risk factors for the occurrence of ADEs of antidepressants during hospitalization.

We deeply appreciate your consideration of our manuscript, and we look forward to receiving comments from the reviewers. If you have any queries, please don't hesitate to contact me at the address below.

Thank you and best regards.

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Sincerely yours,

Xiaojiang Tian

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