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Development of an UPLC-MS/MS method for routine therapeutic drug monitoring of aripiprazole, amisulpride, olanzapine, paliperidone and ziprasidone with a discussion of their therapeutic reference ranges for Chinese patients

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Statement of the Problem: Chinese schizophrenia cases meets a 132% increase from 1990 to 2010 (3.09 vs. 7.16 million). During treatment, therapeutic drug monitoring (TDM) is highly required to compensate individual variation and realize rational medication. Although the AGNP Consensus Guidelines present excellent directions on “therapeutic reference range” for all the frequently used drugs, before introducing it for Chinese patients, significant ethno-cultural variation between Chinese and Caucasians should be carefully considered. Unfortunately, one could find few related data at present time. To fill the gap, the purpose of this study is to establish a highly applicable UPLC-MS/MS method for simultaneous TDM of five anti-schizophrenic drugs and briefly discuss the applicability of AGNP Guidelines for Chinese patients.

Methodology & Theoretical Orientation: An UPLC-MS/MS method for routine therapeutic drug monitoring of aripiprazole, amisulpride, olanzapine, paliperidone and ziprasidone was developed and carefully evaluated. The TDM data from 253 clinical samples was collected and analyzed to investigate applicability of the AGNP therapeutic reference range for Chinese patients.

Findings: Good consistency for olanzapine, aripiprazole, paliperidone and ziprasidone was observed. While for amisulpride, the plasma concentration level (445.2 ± 231.5 ng/mL) was higher than the recommended range (100-320 ng/mL).

Conclusion & Significance: The developed UPLC-MS/MS method is highly suitable for routine TDM usage. And there is necessity of reconstructing a Chinese-specific therapeutic reference range for amisulpride treatment, which would be quite helpful to improve the medication efficiency and safety for Chinese patients.

Biography

Shao-Ting Wang has his expertise in development of novel mass spectrometry methodologies for drug analysis and endogenous biomarker detection. He is the In-charge of the Center of Mass Spectrometry in Renmin Hospital of Wuhan University since 2015 and gained abundant experience on applying chromatography and mass spectrometry techniques in clinical field. After systematic evaluation, reliable laboratory developed tests have been carried out in the center, including newborn screening based on tandem mass spectrometry, therapeutic drug monitoring of anti-schizophrenic and anti-epileptic drugs, and detection of fat soluble vitamins. These contributions significantly promoted the popularization of the chromatography and mass spectrometry techniques for clinical usage in Hubei province of China.

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