Medication related suicidality

Tu-S-346
Detecting signals for medication related suicidality
N. Iessa*, M. Murray*, K. Star, P. Santosh, I. Wong
Centre for Paediatric Pharmacy Research, UCL School of Pharmacy, London, UK
Uppsala Monitoring Centre, Uppsala, Sweden
Institute of Psychiatry, King’s College, London, UK
Department of Pharmacology and Pharmacy, The University of Hong Kong, Hong Kong, China
*Corresponding author.

Background. Suicide related adverse events (SRAEs) associated with medications are of great concern in children and adolescents. Individual case safety reports (ICSRs) held in a worldwide database (VigiBase) are valuable sources of information for early detection of unknown ADRs.

Objectives. Devise a method for generating signals of medication-associated SRAEs from VigiBase. Identify medications with previously unknown potential association to SRAEs.

Method. ICSRs for 2–17 year olds (1968–2010) were screened for potential SRAEs. Summary of Product Characteristics (SPC) were checked to identify medications not known to have SRAEs.

Results. Nineteen drugs in 2–11 and 92 in 12 to 17-year-olds had a SRAE reported. Over 20 Medications-SRAE pairs not documented in SPC were detected.

Discussion. The coded term listed for the SRAE and drug combinations do not reveal if the drug was used for the suicide attempt/completed suicides, unless specified as the ADR (e.g. intentional overdose). Screening individual reports for indicators that can be used to highlight such combinations would be beneficial. The research leading to these results has received funding from the European Community’s Seventh Framework Programme (FP7/2007–2013) under grant agreement No. 261411. This symposium/communication reflects only the author’s views and the European Union is not liable for any use that may be made of the information contained therein.

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Medication related suicidality: Early recognition and assessment
J. Castro-Fornieles*, I. Flamarique, I. Mendez, S. Romero
Child and Adolescent Psychiatry and Psychology Department, Cibersam, Sgr119, Neuroscience Institute, Hospital Clinic of Barcelona, University of Barcelona, Barcelona, Spain
*Corresponding author.

Suicide attempts are frequent in children and adolescents specially related to depressive symptoms. Some data also show an increased risk of self-harm and suicidal thoughts in children and adolescents treated with antidepressants. Probably, subjects at these ages can be more sensitive than adults to adverse activating events such as increased anxiety, restlessness, irritability, anger, akathisia or switch to hypomania. Nevertheless, suicide-related behaviour during psychopharmacological treatment has been a controversial issue during the last years, as a decrease in prescription of antidepressants to children and adolescents has been associated with increased suicide rates. Medication-related suicidality is defined as any suicide-related symptoms reported during the period of treatment. There is a need to balance the assessment of suicidality in mental disorders (especially in depression) and medication-related suicidality. In some studies, there is an inconsistent report of potentially suicidal events that can lead both to under- and over-diagnosis. There has been an inaccurate reporting and assessment, as in many cases, suicidal adverse events information is not systematically elicited but revealed spontaneously.

A scale for children and adolescents assessing all suicide components with items related specifically to medication side effects will be presented. This scale will be validated in different languages. Intervention trials should prospectively and systematically monitor occurrence and emergence of suicidality with consistent and validated methods of assessment. The research leading to these results has received funding from the European Community’s Seventh Framework Programme (FP7/2007–2013) under grant agreement No. 261411. This symposium/communication reflects only the author’s views and the European Union is not liable for any use that may be made of the information contained therein.

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Antidepressants and suicidality
R.W. Dittmann
Department of Child and Adolescent Psychiatry and Psychotherapy, Central Institute of Mental Health, Mannheim, Germany

Based on recent and current literature this presentation will focus on “the use of antidepressant medication and the risk for related suicidality (suicidal ideation, attempt, completed suicide)” as adverse outcomes (adverse events, AEs) in children and adolescents.

Data and findings from retrospective analyses will be summarized and discussed, both from regulatory body (e.g., FDA, EMA) and academic publications (e.g., recently, Gibbons et al., in Arch Gen Psychiatry, Feb 2012).

The current status of available evidence on this topic plus the derived implications for the respective wording in the Summary of Product Characteristics (SPC) of antidepressant compounds will be outlined. Finally, the study protocol outline for a currently planned clinical trial (from the ongoing European FP7 STOP project), comparing two methodological approaches to assess suicidality in a population of fluoxetine-treated paediatric patients with depression, will be presented.

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