Medication related suicidality

Tu-S-345
Ménages d’enfants sans parents au Rwanda : arrachés de l’enfance, projetés dans la responsabilité
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Tu-S-346
Detecting signals for medication related suicidality
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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-SRAEs 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 attempts/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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Tu-S-347
Medication related suicidality: Early recognition and assessment
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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
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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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