Reviewer’s report

Title: Real-Life Assessment of Aripiprazole Monthly (Abilify Maintena) in Schizophrenia: A Canadian Naturalistic Non-Interventional Prospective Cohort Study

Version: 0 Date: 18 Jan 2019

Reviewer: Pirathiv Kugathasan

Reviewer's report:

Dear Authors,

The manuscript regarding the efficacy and effectiveness of Aripiprazole once monthly injectable formulation (AOM) has very important clinical features. While most evidence regarding the effect of antipsychotics are based on RCTs, real world evidence studies are needed to truly understand the real effect on a heterogeneous patient group. The results from this study clearly add valuable knowledge to the current literature of the pros and cons of using Aripiprazole in clinical practice. The manuscript is well written, easy to understand, and reports a clear message. However, there are place for improvement, so below you will find some suggestions and questions that need to be addressed.

#1 Methods - First paragraph. "...patients treated with AOM for schizophrenia for up to 24 months" and later in the inclusion criteria you write the following "Patients diagnosed with schizophrenia spectrum psychosis". It is important that you are clear about the definition of schizophrenia, as some studies prefer F20 (schizophrenia only), while others are more likely to use schizophrenia spectrum disorders (F20-F25), and not to forget the few studies that uses psychosis both within schizophrenia and affective disorders. This is especially necessary to further discuss in the discussion section.

#2 Methods - Right before the description of population. There is an issue regarding the font in the last part of the section - please correct.

#3 Methods - Right before the section of antipsychotic pharmacology. "Both serious as well as non-serious ADR were recorded." Can you please give examples from each of these categories?

#4 Results - 1. Primary outcome; GAF. The citations need to have a reference. Please correct.

#5 Results - The type III test p-value. This kind of test is not described in the statistical analysis section, can you please provide an explanation of this test, because most often p-value and the significance is reported.
#6 Results - 2.2.2. BPRS - "There was no significant between.." Please correct the language here.

#7 Results - 3. Adverse drug reaction. How do you distinguish between "new medication given" and "medication changed" for patients who are already on Aripiprazole?

#8 Discussion. This section "SOFAS is derived from GAF…… Measure in this study" does not belong here, should be described and explained in the methods section. Please correct.

#9 Conclusion - should be more precise and state the main findings and the corresponding clinical implications of them.

#10 Limitations - This section is really weak, there should be more mentioned here. Among others 1) Are there any risk of selection bias for this particular treatment, 2) Is it really the true effect of the drug or the nature of the illness course or even an effect of another intervention, 3) discuss the scales measures, are they reliable? What other alternatives could have been used to assess the effectiveness?

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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