Reviewer’s report

Title: The Sertindole Safety Survey: a retrospective analysis under a named patient-use program in Europe

Version: 2 Date: 14 March 2008

Reviewer: Jari Haukka

Reviewer’s report:

This is potentially interesting study, but description of data acquisition and data analysis need improvement.

I have to request major revision.

Major Compulsory Revisions

Background

More recent information about prevalence and incidence of schizophrenia is provided by Saha et al. (2005) and McGrath et al. (2004). Please consider to use these instead of ref 1 and 2.

@ARTICLE{Saha2005,
  author = {Sukanta Saha and David Chant and Joy Welham and John McGrath},
  title = {A systematic review of the prevalence of schizophrenia.},
  journal = {PLoS Med},
  year = {2005},
  volume = {2},
  pages = {e141},
  number = {5},
  month = {May},
  url = {http://dx.doi.org/10.1371/journal.pmed.0020141}
}

@ARTICLE{McGrath15115547,
  author = {McGrath, John and Saha, Sukanta and Welham, Joy and El Saadi, Ossama and MacCauley, Clare and Chant, David},
  title = {A systematic review of the incidence of schizophrenia: the distribution of rates and the influence of sex, urbanicity, migrant status and methodology},

Methods

More detailed information how data was obtained in each country should be included, names of registers used and other details of data gathering.

Detailed information of case report form should be given (What was recorded in detail!). Is it possible to include the whole form as attachment (extra material) to MS?

More comprehensive description of exposure is needed. Was follow-up stopped at first discontinuation?

How discontinuation was defined? Was e.g. some short period without medication allowed or was discontinuation recorded even with one day without medication?

Was there discontinuation for everyone or was there censoring?

If yes, what was the mechanism of censoring.

Causes of death should be reported more exactly.

Provide ICD-10 codes for suicide and sudden death.

Data analysis

The hazard of discontinuation should be analysed with survival models.

Survival curves and/or also hazards estimates should be presented. Hazard of discontinuation should be analysed using survival models with background variables from case report form.

Table 1.: Add quartiles.

Table 2-4. Independency assumption between rows and columns should be test (e.g. X2-test)

Abstract

In abstract authors state:
"Conclusion: Although prescribing and supplying sertindole were subject to administrative constraints, a significant number of patients were treated with sertindole, thus supporting the need for sertindole in specific cases."
My opinion is that it is not possible to deduce that something is needed from the fact that something is used. This statement is not based on data or analysis presented and should be omitted or rewritten.

Minor Essential Revisions
Numbering of tables should be corrected (Now all are Table 1.)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I have provided small scale consulting service to Cilag-Jansen. No other competing interest.