

Objective:

The aim of the proposal was to meta analyze data from publicly available randomized controlled antipsychotic medication trials in schizophrenia via the OPTICS program (Janssen paliperidone, NIMH CATIE and dbGaP data sets) in order to determine the overall incidence of major gastrointestinal disorders and the relationship between gastrointestinal bowel disorders and the commonly reported secondary effects of antipsychotics including weight gain and metabolic syndrome.

Methods:

The PI obtained access to the study data through the YODA project. Randomized, doubleblind, placebo and active comparator antipsychotic monotherapy trial data from the NIMH CATIE Schizophrenia Distribution 15 has been obtained for subsequent analyses as part of the Open Translational Science in Schizophrenia (OPTICS) project. The participants for these initial analyses were individuals with schizophrenia or schizoaffective disorder from the CATIE phase 1 trials with baseline and post treatment measures available.

Results:

The primary outcome was weight change after accounting for sociodemographic factors. 7.5% percent of the study participants spontaneously reported a GI disorder before study randomization. Of those with a GI disorder, 70.9% reported experiencing gastro-oesophageal reflux disease, followed by 7.9% reporting history of irritable bowel syndrome. The incidence of GI disorder remained the same at the end of the Phase 1/1a. As previously reported, a significant increase in weight gain at the end of Phase 1 was observed, $p = .014$. GI disease did not independently contribute to antipsychotic induced weight gain, $p = .891$.

Conclusions:

Inclusion of additional antipsychotic medication treatment data sets are necessary to replicate prevalence of GI disorders in schizophrenia clinical trials and determine the generalizability of these findings. Future studies including systematic assessment of gastrointestinal diseases and corroborate incidence of gastrointestinal disorders with medical records are needed to confirm preliminary findings. Upon reviewing the data files, there were insufficient numbers of subjects with functional gastrointestinal disorders to complete the objectives of the proposed study. Therefore, the PI decided to discontinue work on this project. All data review was conducted on the secure server. None of the data was downloaded. In addition, the PI is no longer affiliated with the institution where the DUA was initiated.