Article: 2965
Topic: 340 - Satellite Symposium: Satellite Symposium by Lundbeck

HOW TO ASSESS AND STUDY TREATMENT ADHERENCE IN SCHIZOPHRENIA? THE INFLUENCE OF CLINICAL TRIAL DESIGN ON ADHERENCE OUTCOME MEASURES

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The primary goals of maintenance treatment in schizophrenia are sustained symptomatic control, relapse prevention, and delaying functional and cognitive decline.[1] Successful pharmacotherapy is dependent on several factors including efficacy, therapeutic alliance, availability of optimal dosages and formulations, treatment adherence, and a low side-effect burden. New long-acting injectable (LAI) formulations of atypical antipsychotics have been developed to address suboptimal therapy outcomes by enhancing drug delivery, assuring efficacy of treatment, reducing side effects, and improving compliance.[2] Evidence differentiating the effectiveness of oral vs. long-acting antipsychotics is difficult to obtain in randomized controlled trials (RCTs) where adherence to both is optimized.

RCTs are designed to establish clinical efficacy in an “ideal” setting in which medication adherence is controlled and highly regulated.[3] However, RCTs cannot by definition assess treatment effectiveness. Conversely, naturalistic studies that mimic clinical practice are more likely to uncover real-world effectiveness differences of different treatment options. Research has demonstrated major benefits of LAIs in naturalistic studies, including large, nationwide cohort studies and mirror-image studies where patients serve as their own controls. Results from these trials are likely to be underestimated in RCTs owing to stringent inclusion criteria, frequent clinic visits and direct provision of medications.[4] Therefore, data from meta-analyses can be misleading if the trial design is not considered in the interpretation of the results.[5] Furthermore, naturalistic studies can more accurately assess the consequences for patients with regards to relapse and rehospitalization rates. Therefore, clinicians have to be aware of the origin of data and its impact on the results before making treatment decisions.

The current presentation will critically review data from 3 meta-analyses comparing LAIs with oral antipsychotics, exploring how to interpret the data from different trial designs in the context of unmet patient needs, and how the results from differential designs may impact treatment outcomes.

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https://doi.org/10.1016/S0924-9338(13)77494-7 Published online by Cambridge University Press