

Abstract

Background. Schizophrenia affects individuals, families, and systems, with treatment primarily being antipsychotic medications. Long-acting injectable (LAI) antipsychotics are increasingly being used. This study sought to identify predictors of antipsychotic choice, in terms of formulation (LAI vs oral) and class (FGA vs SGA), and clinical outcomes.

Methods. 123 patients who received LAI antipsychotics were diagnosis-matched to patients who received oral antipsychotics. Sociodemographic and clinical factors were extracted from the medical record, including indicators of illness severity. Groups were compared with Chi-Square and t-tests, and logistic regression models were used to identify independent predictors of antipsychotic choice.

Results. Patients that received LAIs had longer admissions, more complex discharges, and greater illness severity; however, there were no differences in readmission rates. Independent predictors of LAIs included younger age, being single, and longer admission. Patients who received FGA LAIs were more likely to use substances and be undomiciled compared to SGA LAIs, with the only predictor being older age. Oral FGAs were more likely than oral SGAs to be prescribed to older and female patients, as well as those with co-occurring substance use, complex discharges, and longer admissions.

Conclusions. Illness severity and duration of illness appear to drive choice of LAI vs. oral antipsychotic medication and FGA vs. SGA. While LAIs were prescribed to patients with greater illness severity, readmission rates were equivalent to those receiving oral medication, supporting the use of LAI in patients with greater illness severity. Rationales for prescribing LAIs to younger patients and FGAs to older patients are discussed.

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Complete *in vitro* Dissolution of Valbenazine as Either Whole Capsules or Crushed Capsule Contents

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Abstract

Introduction. Tardive dyskinesia (TD) is a persistent and potentially disabling movement disorder associated with exposure to antipsychotics and other dopamine receptor blocking agents. Three valbenazine capsule strengths (40 mg, 60 mg, 80 mg) are approved for the once-daily treatment of TD. However, some patients with TD, especially in elderly populations, have trouble swallowing due to orolingual movements. This study was conducted to evaluate two different dissolution methods for valbenazine: whole intact capsules versus crushed capsule contents.

Methods. Samples were prepared using two commercial lots (Lot-A, Lot-B) for two doses (40 mg, 80 mg), with six replicate

samples per lot and dose. The whole capsules were weighed, put into a sinker, and added to a dissolution bath containing 900 mL of 0.1N HCl at $37 \pm 0.5^\circ$ Celsius. Testing on the crushed capsule contents commenced after opening the capsules, weighing and crushing the contents, and transferring the contents to the dissolution bath. Samples were collected (at 10, 15, 20, 30, 45, and 60 min) with a paddle speed of 50 rpm and analyzed using high performance liquid chromatography. Standards were prepared at nominal concentrations of 0.044 mg/mL (for 40 mg) and 0.089 mg/mL (for 80 mg).

Results. Capsules were opened easily by manual manipulation, and contents were crushed easily between spoons. Very rapid (>85% in 15 min) and complete drug release was observed in all samples, independent of capsule strength (40 mg, 80 mg) or preparation (whole intact capsule or crushed capsule contents). For 40-mg capsules, average percent release at first and last collection timepoints were as follows (whole vs crushed): 10 min (98.4% vs 98.6% [A], 93.7% vs 97.6% [B]); 60 min (102.3% vs 100.5% [A], 100.9% vs 100.6% [B]). Results for 80-mg capsules were as follows: 10 min (98.2% vs 99.6% [A], 99.4% vs 97.9% [B]); 60 min (102.0% vs 101.6% [A], 103.2% vs 100.9% [B]).

Conclusions. Crushing the capsule contents did not impact the *in vitro* dissolution performance of valbenazine. Many patients with TD, particularly elderly patients, have difficulty swallowing and may benefit from alternative delivery methods for valbenazine, especially if other TD medications cannot be crushed. More research is needed to better understand if and how crushing the capsule contents of valbenazine affects their stability when mixed with food or delivered through a feeding tube.

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Digital CBT-I Treatment Improves Sleep and Reduces Anxiety and Depression Symptoms in Adults With Chronic Insomnia: Interim Analysis of DREAM Study

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Abstract

Introduction. Chronic insomnia (CI) often co-occurs with depression and anxiety, and treatment may positively impact mood. This ongoing study collected real-world data on changes in insomnia, depression, and anxiety symptoms among adults with CI treated with a prescription digital therapeutic (PDT) delivering cognitive-behavioral therapy for insomnia (CBT-I; Somryst, previously SHUTi).

Methods. This prospective, single-arm, pragmatic clinical study enrolled adults (≥ 18 years) in the US with CI and mobile device access. The PDT consists of six core modules completed over