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TIME COURSE OF ADVERSE EVENTS

Descriptive data analysis of a schizophrenia relapse prevention trial of cariprazine

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The incidence of adverse drug reactions with cariprazine decreased over time.

Adverse events with cariprazine were associated with relatively low discontinuation rates.

INTRODUCTION

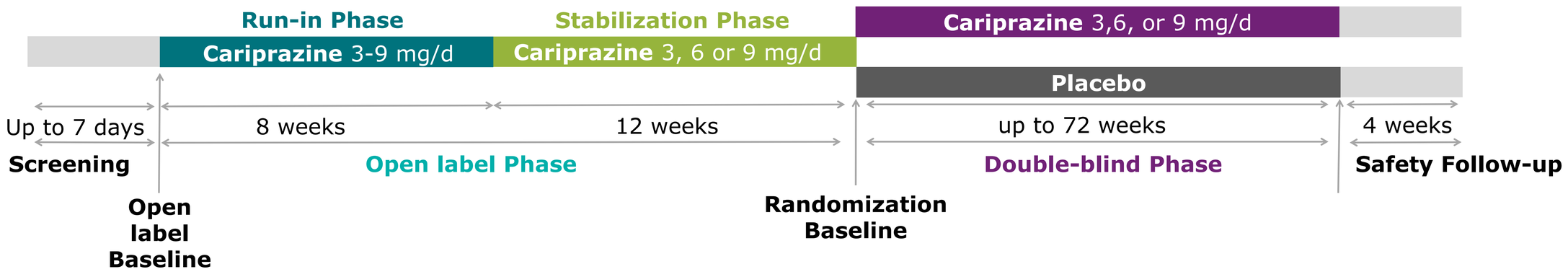
Cariprazine is an atypical, dopamine receptor partial agonist antipsychotic, with preferential binding to D3 receptors, thus being unique among antipsychotics in having a higher potency for the D3 receptor than the D2 receptor, which may contribute to a different efficacy and safety profile compared to other agents. [1]

OBJECTIVE

To determine the period when most adverse events in the course of cariprazine treatment emerge during a trial with a cariprazine run-in, stabilization and double-blind continuation phase, and analyse the relationship between adverse effects and treatment discontinuation

METHODS

- Post-hoc analysis of safety data from a long-term trial of cariprazine (NCT01412060) that evaluated the efficacy, safety, and tolerability of cariprazine for relapse prevention in adults with schizophrenia [2] .
- The study consisted of the following periods:
  - **Screening phase** (≤ 7 days),
  - **Open-label phase**, including: **Run-in phase** (8 weeks) and **Stabilization phase** (12 weeks),
  - A placebo controlled **Double-blind phase** (variable length 26 to 72 weeks), and
  - **Safety follow-up** phase (4 weeks).
- A descriptive analysis was performed for the above defined phases with regards to the most common (≥10%) adverse events (AE) occurring in the open label phase: akathisia, movement disorders except for akathisia, headache, and sleep disorders (insomnia and sedation/somnolence).



RESULTS

- The occurrence of most common adverse events are presented in Figure 1a & 1b.
- Discontinuation rates are presented in Table 1.

Figure 1/a. The most common (≥10%) AEs

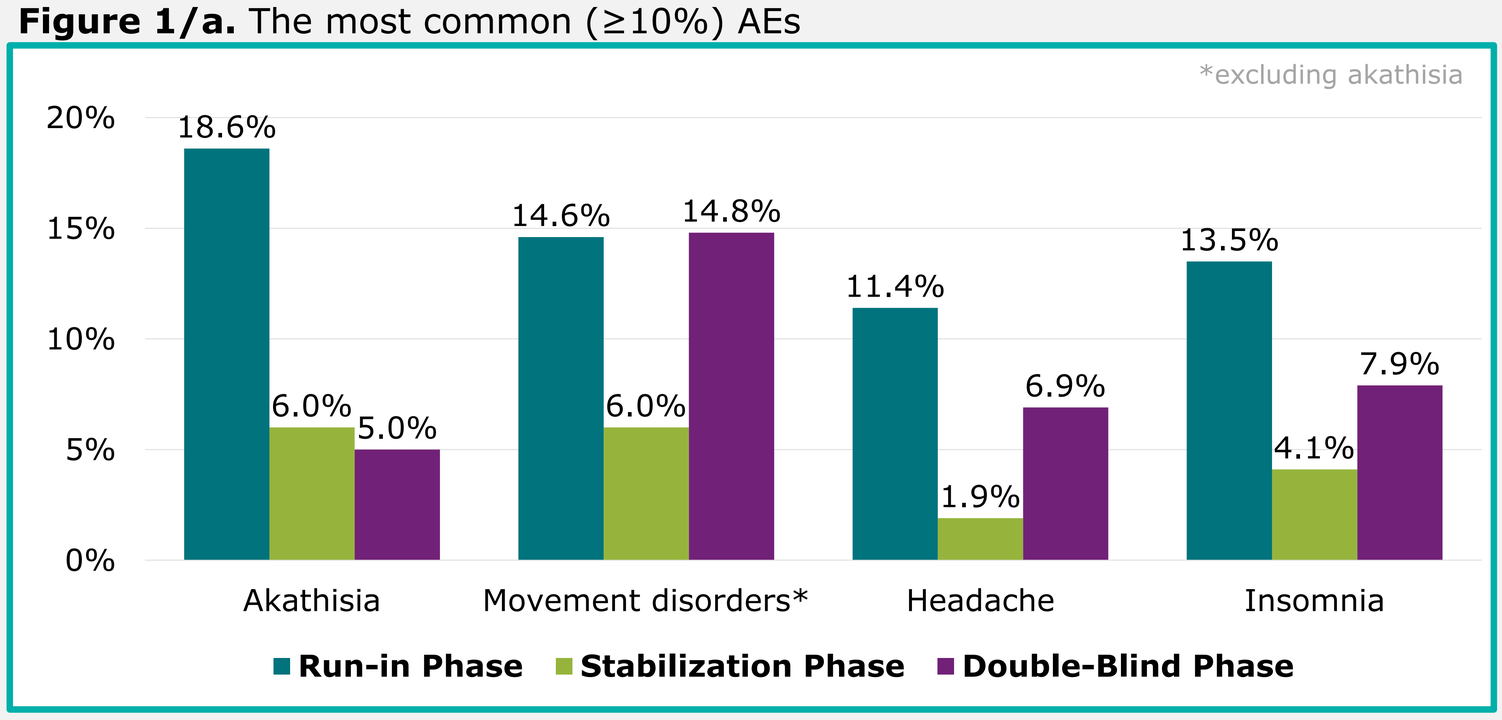
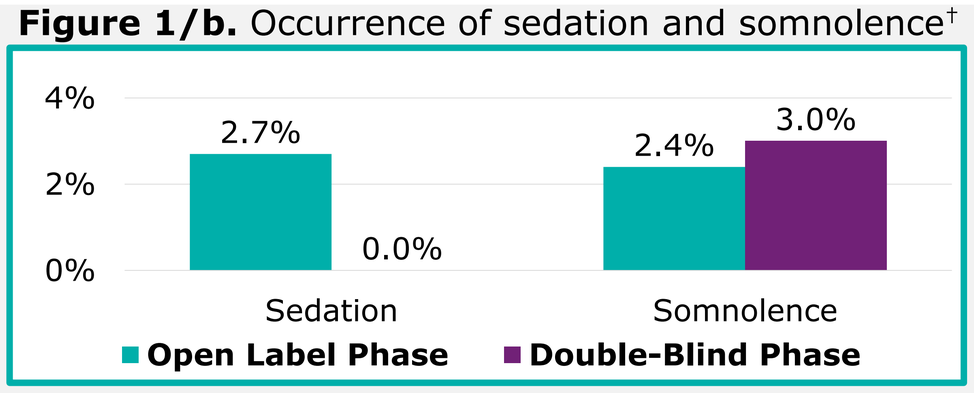


Figure 1/b. Occurrence of sedation and somnolence†



†Data only for open label phase as a whole

Table 1. Discontinuation rates due to each EA

Adverse Event	Discontinuation rate**
Akathisia	1.0%
Movement disorders*	0.7%
Headache	0.13%
Insomnia	0.8%
Sedation	0%
Somnolence	0%

***All discontinuations occurred in the Open Label Phase*

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[1] Stahl, S. M. (2016). Mechanism of action of cariprazine. CNS Spectrums, 21(2), 123–127. https://doi.org/10.1017/s1092852916000043 [2] Durgam, et al. (2016). Long-term Cariprazine treatment for the prevention of relapse in patients with schizophrenia: A randomized, double-blind, placebo-controlled trial. Schizophrenia Research, 176(2-3), 264–271. https://doi.org/10.1016/j.schres.2016.06.030.

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