Limited treatment options are available for patients with central hypersomnia, and many patients continue to have significant symptoms despite use of established therapies. Pitolisant is a novel wakefulness-promoting agent which has been demonstrated to reduce sleepiness in treatment naïve patients with narcolepsy. Little is known about the utility of Pitolisant therapy in patients whose symptoms are refractory to other available medications. We assessed outcomes in hypersomnia patients who were resistant to or intolerant of conventional stimulant therapy.

Patients with objectively confirmed central hypersomnia, who had persistent EDS despite use of ≥2 wakefulness-promoting agents, were commenced on Pitolisant via a pharmacist-led medication management clinic. We prospectively recorded the Epworth Sleepiness Scale (ESS), Pittsburgh Sleep Quality Index (PSQI), and quality of life scores (EQ-5D visual analogue scale) at initiation and after 12 weeks of Pitolisant therapy. For the purposes of this analysis we defined responders as those with a reduction in ESS of ≥2.

A total of 38 patients were given Pitolisant (55% female; 66% NTI1; age 41.2±13.5 years). 6 stopped treatment due to adverse effects (50% insomnia; 33% apparent allergic reaction). Among those who completed 12 weeks of therapy, ESS reduced from 18.4±4.1 to 15.5±5.1 (p=0.001), PSQI reduced from 10.5±3.4 to 8.4±4.5 (p=0.006), and EQ-5D improved from 52±22 to 63±19 (p=0.004). Of the cohort, 17 (45%) were defined as responders – no significant differences in demographic factors, underlying diagnosis, or baseline symptom burden were observed between responders and non-responders.

In a cohort of patients with difficult to treat central hypersomnia, Pitolisant therapy led to a reduction in daytime sleepiness and improved quality of life scores in a significant proportion of patients. Pitolisant may be a useful adjuvant therapy in some patients with treatment refractory hypersomnia.

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