LETTER TO THE EDITOR

Effect of Lemborexant in Elderly Insomnia Patients

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ABSTRACT

Objective: **We retrospectively examined the efficacy of lemborexant in elderly insomnia patients.**

Methods: **Insomnia was assessed using the Athens Insomnia Scale (AIS). Efficacy outcome assessment was the Clinical Global Impressions-Improvement scale (CGI-I).**

Results: **Of 34 patients, 15 (male/female; 2/13) patients had recently started lemborexant and 19 (male/female; 2/17) patients had switched from benzodiazepine hypnotic monotherapy to lemborexant. The 24-week continuation rate for lemborexant was 84.4%. The mean AIS total score improved significantly after 24 weeks of treatment (from 6.0 ± 2.6 to 4.9 ± 2.8) ($p < 0.05$). The mean CGI-I score was 3.5 ± 0.7.**

Conclusion: **The results of our study suggest that lemborexant may be safe and effective in elderly insomnia patients in real-world clinical practice.**

KEY WORDS

lemborexant, elderly, efficacy, treatment discontinuation, insomnia

INTRODUCTION

Benzodiazepine hypnotics are frequently used in real-world clinical practice but are notorious for their various adverse effects, such as their addictive potential, withdrawal symptoms, cognitive impairments, and dementia, as well as increased mortality, especially in the elderly. On the other hand, the orexin receptor antagonist lemborexant has a low dependence potential, and less effect as a muscle relaxant and on cognitive function. Therefore, it has potential as an insomnia medication that lacks the problematic side effects of other pharmacological treatment options. In previous research, we reported the effectiveness of lemborexant treatment (Suzuki and Hibino, 2021). In addition, we retrospectively examined the efficacy of lemborexant in elderly insomnia patients.

The participants enrolled in this retrospective study were outpatients at Suzuki Clinic. All participants were diagnosed with insomnia disorder based on the guidelines of the DSM-V, and were followed up for 6 months after their first lemborexant prescription. The observation period lasted from July 2020 (when it was introduced for clinical use) to December 2020. Insomnia was assessed using the Athens Insomnia Scale (AIS). The efficacy outcome assessment used was the Clinical Global Impressions-Improvement scale (CGI-I). This study was approved by the ethics committee of Fukui Kinen Hospital. We compared patient background characteristics and AIS and CGI-I scores with the Mann-Whitney U test and estimated the treatment continuation rate using Kaplan ―Meier survival analysis. The significance level was set at $P < 0.05$.

Of 34 patients, 15 (male/female; 2/13) patients had recently started lemborexant and 19 (male/female; 2/17) patients had switched from benzodiazepine hypnotic monotherapy to lemborexant. The mean subject age was 76.3 ± 11.6 years. The average dose of lemborexant was 5.6 ± 2.1 mg. The mean AIS total score improved significantly after 24 weeks of treatment (from 6.0 ± 2.6 to 4.9 ± 2.8) ($p < 0.05$). The mean CGI-I score was 3.5 ± 0.7. The 24-week continuation rate for lemborexant was 84.4% (Fig. 1). In the present study, patients discontinued treatment for the following reasons: sleepiness and fatigue (n = 3), nightmares (n = 1), and other (n = 1). All adverse events were mild and transient and completely resolved themselves after discontinuation.

DISCUSSION

This study was conducted under the assumption that continued medication usage meant that the treatment was progressing well. Similar to results obtained in previous studies (Lieberman et al. 2005), the 6-month continuation rate of lemborexant in the present study was relatively high, both the CGI-I score, which is an objective indicator evaluated by therapists, and the AIS, which is a subjective evaluation of patients, also improved (Kärppä *et al*. 2020). In contrast, previous studies suggested that lemborexant affected lightheadedness and cognitive function little when waking up (Rosenberg *et al*. 2020). Similar to the results of previous studies, the treatment interruption rate was low for adverse events and no serious adverse events were observed in this study (Beuckmann *et al*. 2019). The results of our study suggest that lemborexant may be safe and effective in elderly insomnia patients in real-world clinical practice. However, due to selection bias, the results should be interpreted with caution. In addition, it had a small sample size, short research period, and it was not double-blinded.

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