

Effectiveness of Vonoprazan on Health-related Quality of Life and Sleep Quality in Chinese Patients with Reflux Esophagitis: Post Hoc Analysis of the VIEW Study

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Introduction

- Reflux esophagitis (RE) commonly occurs in patients with gastroesophageal reflux disease (GERD), and is the result of acid reflux causing inflammation and damage to esophageal mucosa¹
- While typical symptoms of GERD/RE include heartburn and/or regurgitation, patients may also experience sleep disturbances and psychological effects such as anxiety and depression¹⁻⁴
- RE can thus negatively impact patients' health-related quality of life (HRQoL)
- Vonoprazan, a novel oral potassium-competitive acid blocker, is approved as first-line treatment for RE in China^{5,6}
 - Vonoprazan has shown superior potency and longer duration of action compared with conventional proton pump inhibitors⁵
- However, there is limited real-world data on the impact of vonoprazan on HRQoL

Objective

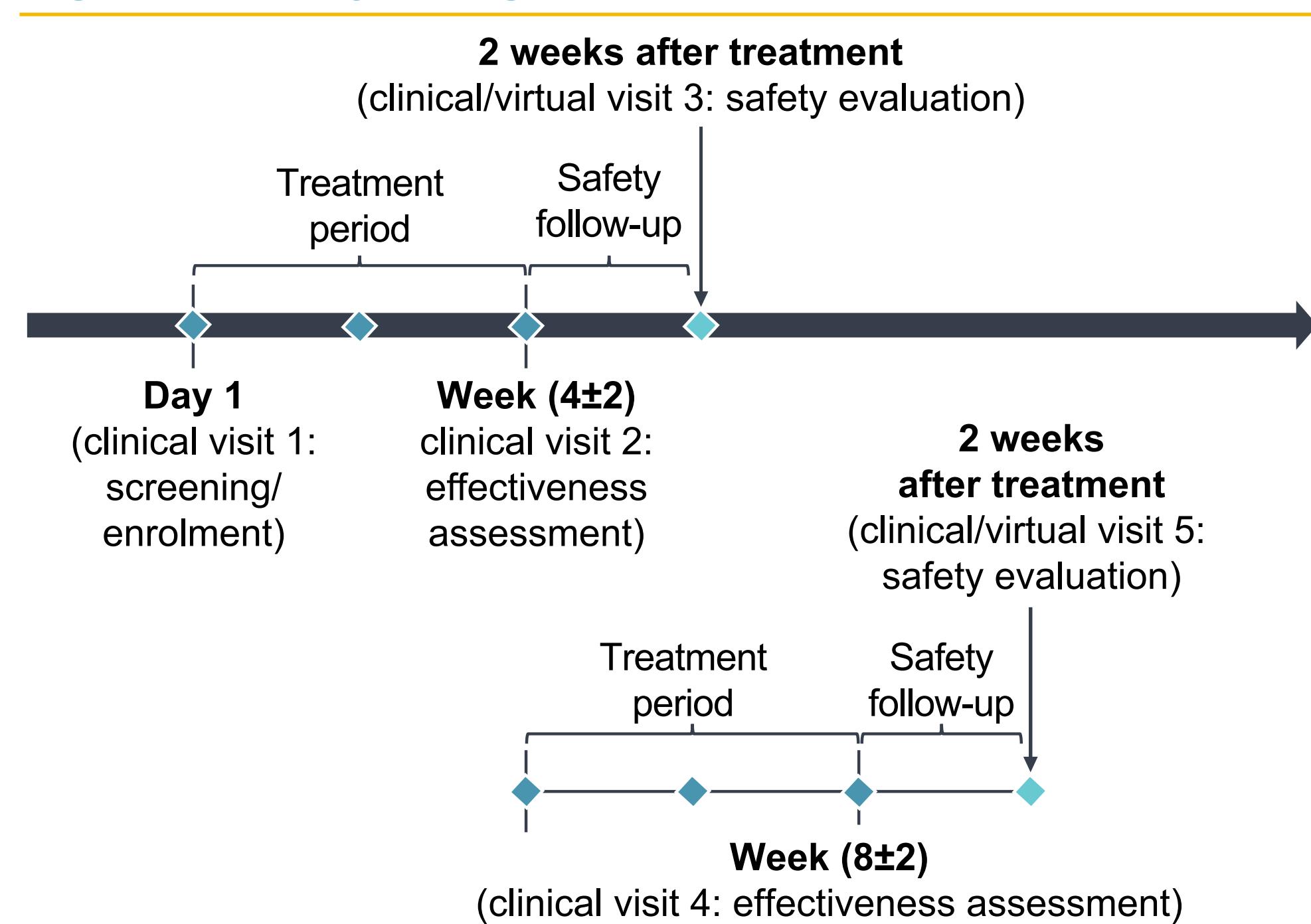
This post hoc analysis of the VIEW study (NCT04501627) evaluated the effectiveness of vonoprazan treatment on HRQoL and sleep quality in patients with RE in a real-world clinical setting

Methods

Study Design

- VIEW was a multicenter, single-arm, prospective, observational study conducted in China (Figure 1)
 - Patients (aged ≥ 18 years) prescribed 20 mg vonoprazan, once daily for 4 weeks (8 weeks for insufficient healing) were enrolled

Figure 1. Study Design



Post Hoc Analysis Assessments

EuroQol 5-Dimension 5-Level (EQ-5D-5L)

- Percentage of patients with different levels of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression at baseline and Week 4

Pittsburgh Sleep Quality Index (PSQI)

- In patients with poor sleep quality (PSQI > 5 points) at baseline, the proportion with improved sleep quality (PSQI ≤ 5 points) at Week 4, stratified by complete versus with incomplete symptom relief in the first week of treatment
 - Complete symptom relief during the first week is defined as patients' symptom score (recorded using patient diaries) equal to 0, consecutively from Day 1 to Day 7; a symptom score > 0 is considered incomplete symptom relief

Statistical Analysis

- The safety analysis population for patients with RE consisted of patients who received ≥ 1 dose of vonoprazan and provided safety information
- The effectiveness analysis set for patients with RE consisted of patients in the safety analysis population who had ≥ 1 effectiveness endpoint assessment in clinical visit 2 (week 4±2) or clinical visit 4 (week 8±2)

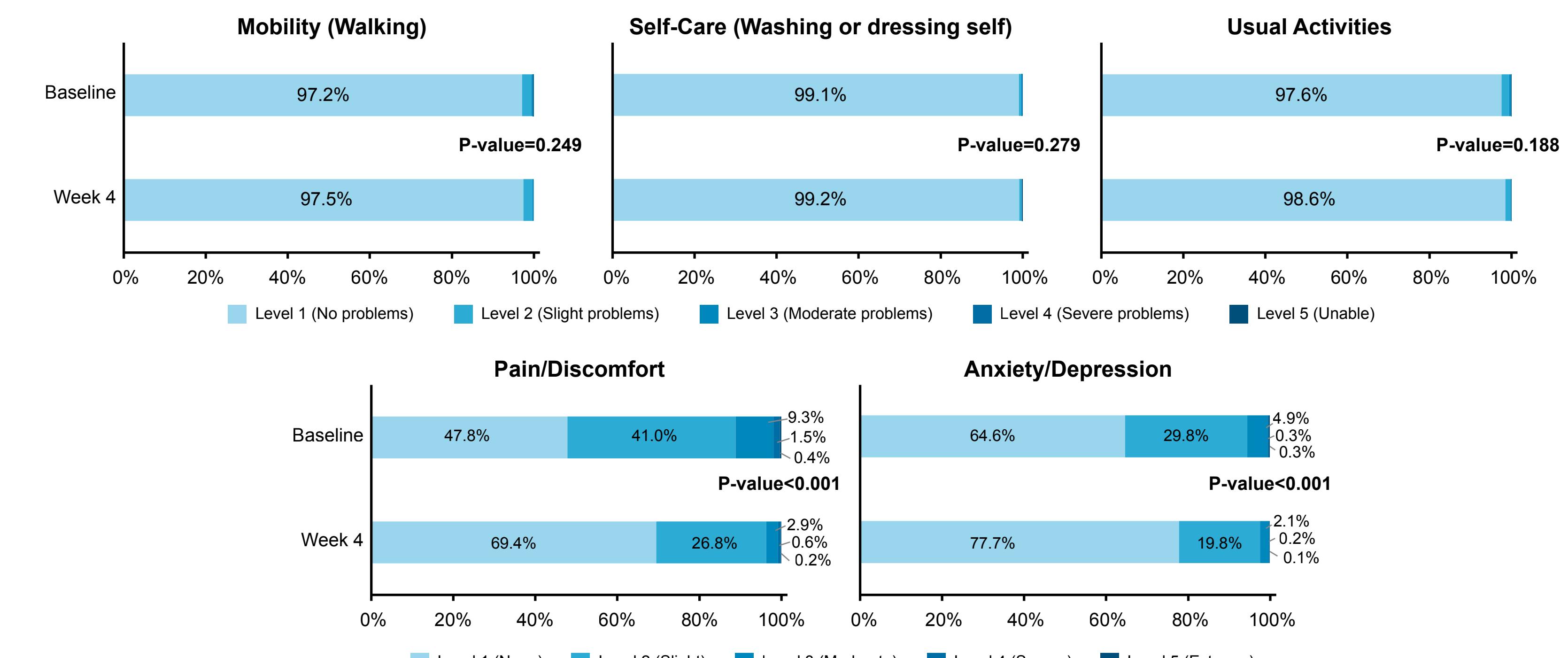
Results

- A total of 1877 patients were included in the RE safety analysis population, of which 1796 were part of the effectiveness analysis set
- The mean (standard deviation) age and body mass index were 49.7 (13.4) years and 24.1 (3.5) kg/m², respectively.

Distribution of EQ-5D-5L Dimension Levels

- Significant differences in the distribution of EQ-5D-5L dimension levels for pain/discomfort and anxiety/depression were observed at Week 4 versus baseline (Figure 2)
 - The percentage of patients with no pain/discomfort and no anxiety/depression increased from 47.8% to 69.4% and 64.6% to 77.7%, respectively
 - No significant differences in the distribution of levels for mobility, self-care and usual activities were observed

Figure 2. Distribution of EQ-5D-5L Dimension Levels at Baseline and Week 4 (Effectiveness Analysis Population)

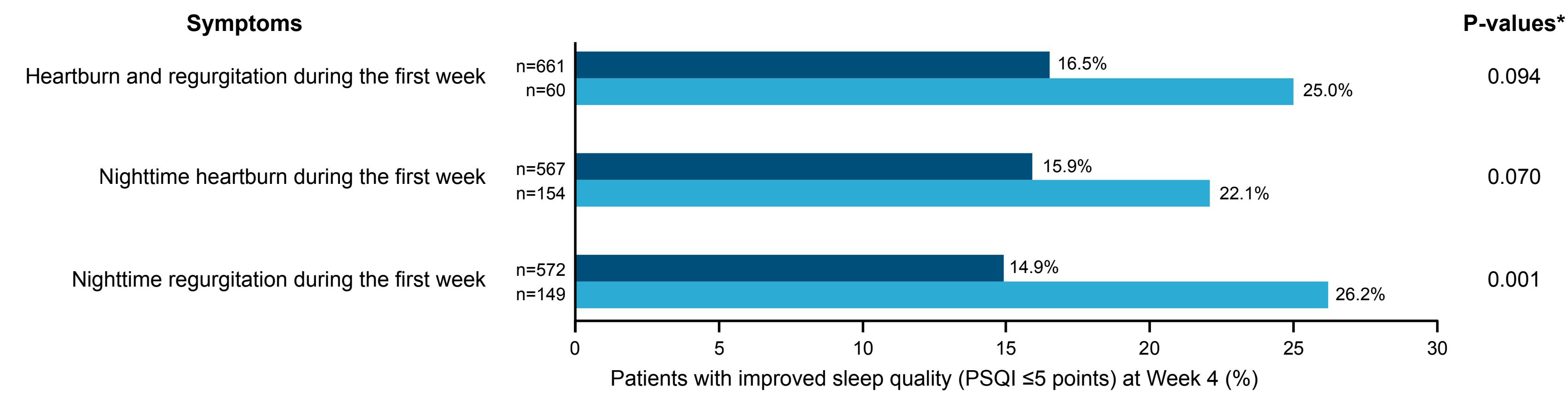


EQ-5D-5L, EuroQol 5-Dimension 5-Level; RE, reflux esophagitis.

Relationship between Improved Sleep Quality and Improved Symptoms

- Among the 721 patients with poor sleep quality at baseline, significantly more patients with complete relief from nighttime regurgitation during the first week had improved sleep quality at Week 4 versus those with incomplete relief (26.2% vs 14.9%, P=0.001; Figure 3)
- Similar trends, although nonsignificant, were observed for heartburn and regurgitation (25.0% vs 16.5%, P=0.094) and nighttime heartburn (22.1% vs 15.9%, P=0.070), with a higher proportion of patients with complete relief vs those with incomplete relief during the first week, experiencing better sleep quality by Week 4

Figure 3: Improvement in Sleep Quality (PSQI ≤ 5 Points) at Week 4 for Patients with Complete or with Incomplete Symptom Relief during the First Week (Effectiveness Analysis Population)



*P-value calculated using Pearson's chi-square test.

PSQI, Pittsburgh sleep quality index; RE, reflux esophagitis.

Conclusions

- Vonoprazan treatment in real-world clinical practice improved HRQoL and sleep quality among Chinese patients with RE
- After 4 weeks of treatment:
 - Patients' quality of life improved from baseline, specific to pain/discomfort and anxiety/depression levels
 - Patients with complete relief from nighttime regurgitation during Week 1, had significantly better sleep quality than those with incomplete relief

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Conflicts of interest

Yinglian Xiao has no conflicts of interest; Kailun Liang and Fang Zhou are Takeda employees and hold Takeda stock options. Minhu Chen received speaker honoraria from Takeda China, AstraZeneca China, Xian Janssen and Eisai China.

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