

Symptom Relief with Vonoprazan Treatment in Gastroesophageal Reflux Disease Patients with Diabetes in China: Post Hoc Analysis of the VIEW Study

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Introduction

- A significant association is reported between diabetes mellitus and the risk of gastroesophageal reflux disease (GERD)^{1,2}
 - This association is more pronounced among Asian patients compared with their Western counterparts¹
- Proton pump inhibitors (PPIs) are prescribed to treat GERD.² However, GERD patients with diabetes are significantly more likely to experience treatment failure than those without diabetes³
- Vonoprazan is a novel oral potassium-competitive acid blocker, approved as first-line treatment for reflux esophagitis (a common phenotype of GERD) in China^{4,5}
 - Vonoprazan has shown superior potency and longer duration of action compared with conventional PPIs⁴
- However, there is a lack of data on the effectiveness of vonoprazan among GERD patients with diabetes

Objective

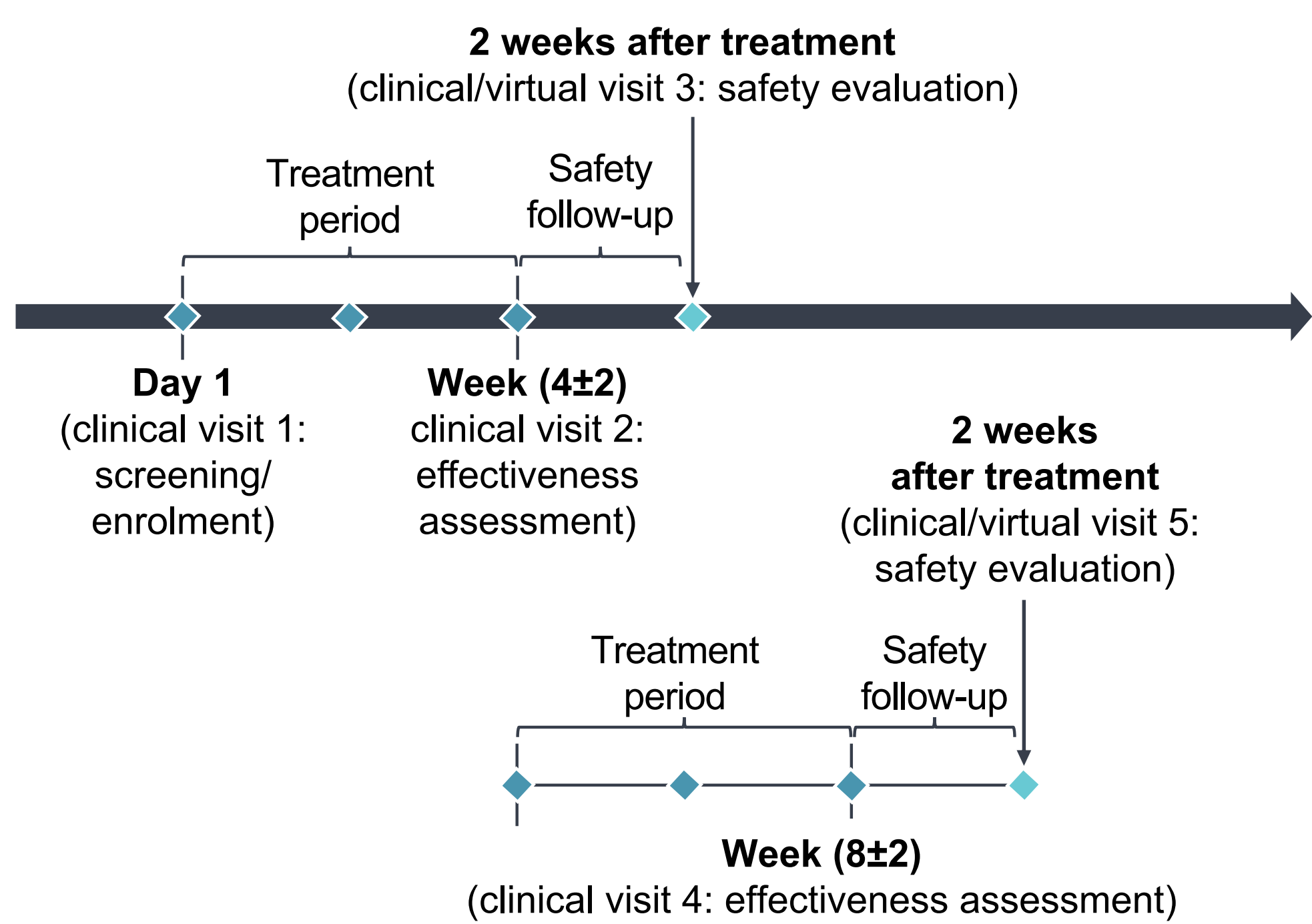
This post hoc analysis of the VIEW study (NCT04501627) evaluated the effectiveness of vonoprazan treatment for symptom relief among GERD patients with diabetes in a real-world clinical setting

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 assessments in GERD patients with diabetes

- Changes in symptom scores (recorded in patients' diaries) from baseline during the first 14 days of treatment
- Cumulative percentage of patients with complete symptom relief from day 1 to day 14
 - Complete symptom relief is defined as patients' symptom score equal to 0
- First heartburn and regurgitation symptom relief rate
 - Heartburn and regurgitation symptom relief is defined as daytime and nighttime heartburn and regurgitation score equal to 0

Statistical analysis

- The effectiveness analysis population consisted of patients with GERD who have taken ≥1 dose of vonoprazan in routine care, provided safety information, and who have ≥1 effectiveness endpoint assessment in clinical visit 2 (Week 4±2) or clinical visit 4 (Week 8±2)
- A mixed-effects model was utilized for repeated measures analysis, and changes in least-squares mean (LSM) symptom scores were reported (negative values indicate improvement)
- Symptom relief rate was based on the Kaplan-Meier method

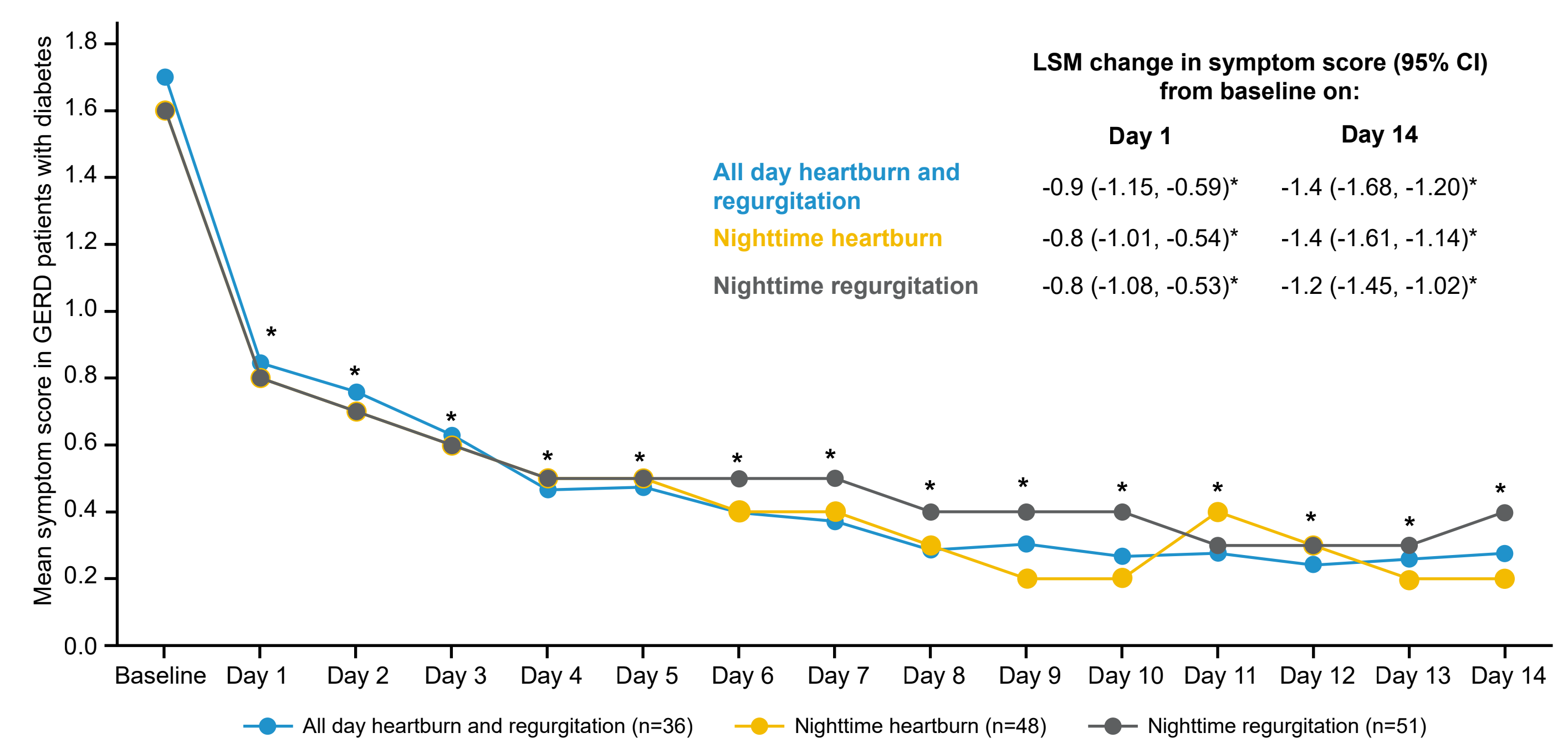
Results

- Of the 2214 patients in the effectiveness analysis population for GERD, 106 (4.8%) had diabetes

Symptom scores during the first 14 days of treatment in GERD patients with diabetes

- In GERD patients with diabetes and all-day heartburn and regurgitation, vonoprazan significantly reduced the mean symptom scores from 1.7 at baseline (n=36) to 0.8 on day 1 (n=29) and to 0.3 by day 14 (n=29) (**Figure 2**)
 - Similarly, significant improvements were observed in patients with nighttime heartburn, with mean scores reducing from 1.6 at baseline (n=48) to 0.8 on day 1 (n=40) and to 0.2 by day 14 (n=40); for nighttime regurgitation, the mean scores reduced from 1.6 at baseline (n=51) to 0.8 on day 1 (n=42) and to 0.4 by day 14 (n=40)
- The LSM change in symptom scores from baseline to day 14 demonstrated a significant improvement in all-day heartburn and regurgitation, nighttime heartburn, and nighttime regurgitation in GERD patients with diabetes (**Figure 2**)

Figure 2. Mean symptom scores from baseline to day 14 in GERD patients with diabetes

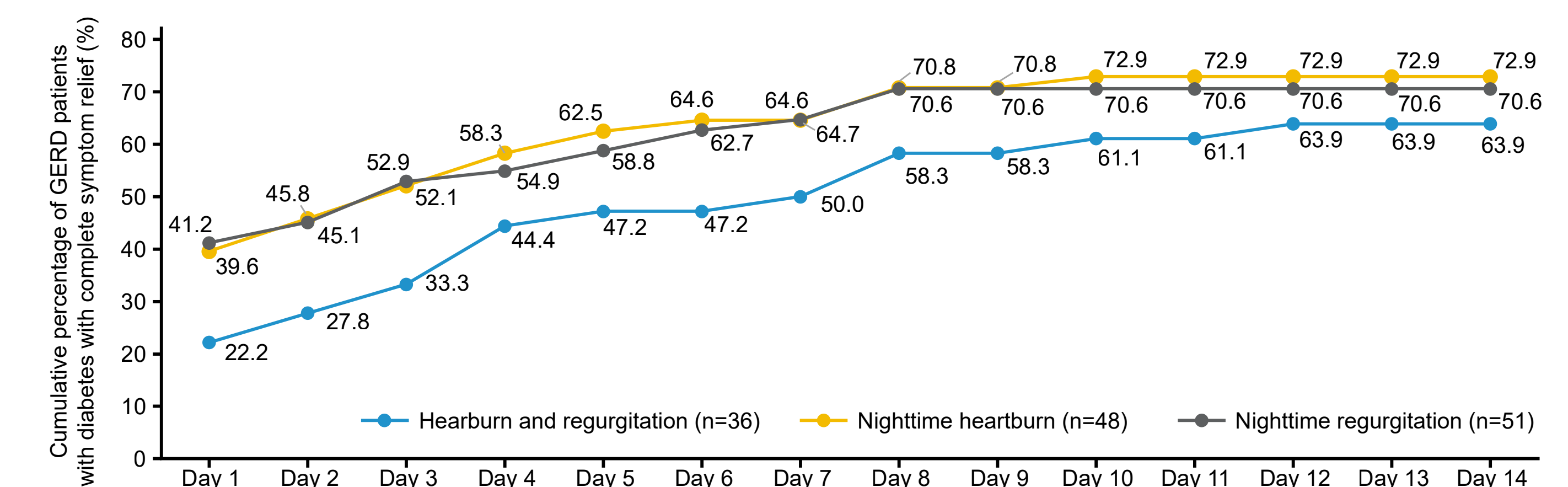


Symptoms were scored on a scale from 0 (none) to 3 (severe).
*Indicates P-value <0.001 vs baseline.
CI, confidence interval; GERD, gastroesophageal reflux disease; LSM, least-squares mean.

Cumulative percentage of GERD patients with diabetes with complete symptom relief during the first 14 days of treatment

- The cumulative percentage of GERD patients with diabetes who experienced complete symptom relief from heartburn and regurgitation, nighttime heartburn, and nighttime regurgitation increased from 22.2% (n=8) to 63.9% (n=23), 39.6% (n=19) to 72.9% (n=35), and 41.2% (n=21) to 70.6% (n=36), from Day 1 to Day 14, respectively (**Figure 3**)

Figure 3: Cumulative percentage of GERD patients with diabetes with complete symptom relief from day 1 to day 14



GERD, gastroesophageal reflux disease.

Symptom relief rate

- Among GERD patients with diabetes who had both heartburn and regurgitation at baseline (n=36), the rate of symptom relief from first heartburn and regurgitation was 37.0% on day 3, increasing to 77.8% by day 14 (**Table 1**)

Table 1: First Heartburn and Regurgitation Symptom Relief in GERD patients with diabetes

	First heartburn and regurgitation symptom relief rate (%) (95% CI) (n=36)
By day 3	37.0 (22.70, 56.45)
By day 7	59.3 (42.18, 77.04)
By day 14	77.8 (61.15, 90.86)

CI, confidence interval; GERD, gastroesophageal reflux disease.

Conclusions

Results from this post hoc analysis of the VIEW study demonstrated effective symptom relief with vonoprazan treatment in GERD patients with diabetes in a real-world setting

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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. Minlu Chen received speaker honoraria from Takeda China, AstraZeneca China, Xian Janssen and Eisai China.

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