Patient Reported Outcomes of Vonoprazan in Chinese Reflux Esophagitis Patients: A Prospective Real-World Study

Yinglian Xiao[1], Zhanxiong Xue[2], Zhenyu Zhang[3], Qi Song[4], Li Xie[4], Minhu Chen[1]

[1]The First Affiliated Hospital, Sun Yat-Sen University, Guangzhou, China.[2] The Second Affiliated Hospital of Wenzhou Medical University, Wenzhou, China. [3] Nanjing First Hospital, Nanjing, China. [4] Takeda (China) International Trade Co., Shanghai, China.

Poster No: CO166

BACKGROUND

- Reflux esophagitis (RE), a phenotype of gastroesophageal reflux disease (GERD) is an oesophageal mucosal injury with an estimated prevalence of 6.4% in China.[1]
- Gastroesophageal reflux disease can significantly affect a patient's quality of life (QoL). Therefore, the main aim of treatment is to improve QoL. For the last two decades, proton pump inhibitors (PPIs) have been the primary treatment for GERD.[2]
- In China, PPIs have been approved to improve the QoL of GERD patients. However, PPIs have several limitations such as improper acid control and nocturnal acid breakthrough.[3]
- Vonoprazan (VPZ), a novel potassium-competitive acid blocker, has been approved in China after exhibiting clinical benefit in RE.[4]
- Patient-reported outcomes (PROs) are direct patient-reported tools that inform clinicians, patients, and policy-makers about symptoms, health-related QoL, and patient-perceived health status, thus indicating morbidity and patient suffering.[5]
- VIEW (NCT04501627) is a multicenter, single-arm, prospective, non-interventional study of vonoprazan, conducted in China. Here, we present the results of changes from baseline to week 4 in PROs for overall and for elderly (≥65 years) RE patients. [6]

OBJECTIVE

To evaluate the effectiveness of vonoprazan in QoL and quality of sleep for Chinese RE patients treated with vonoprazan in real-world clinical practice: in the overall patient population and elderly (≥65 years) patients' subgroup.

METHODS

Study design:

Multicenter, single-arm, prospective, observational, non-interventional, real-world study in China.
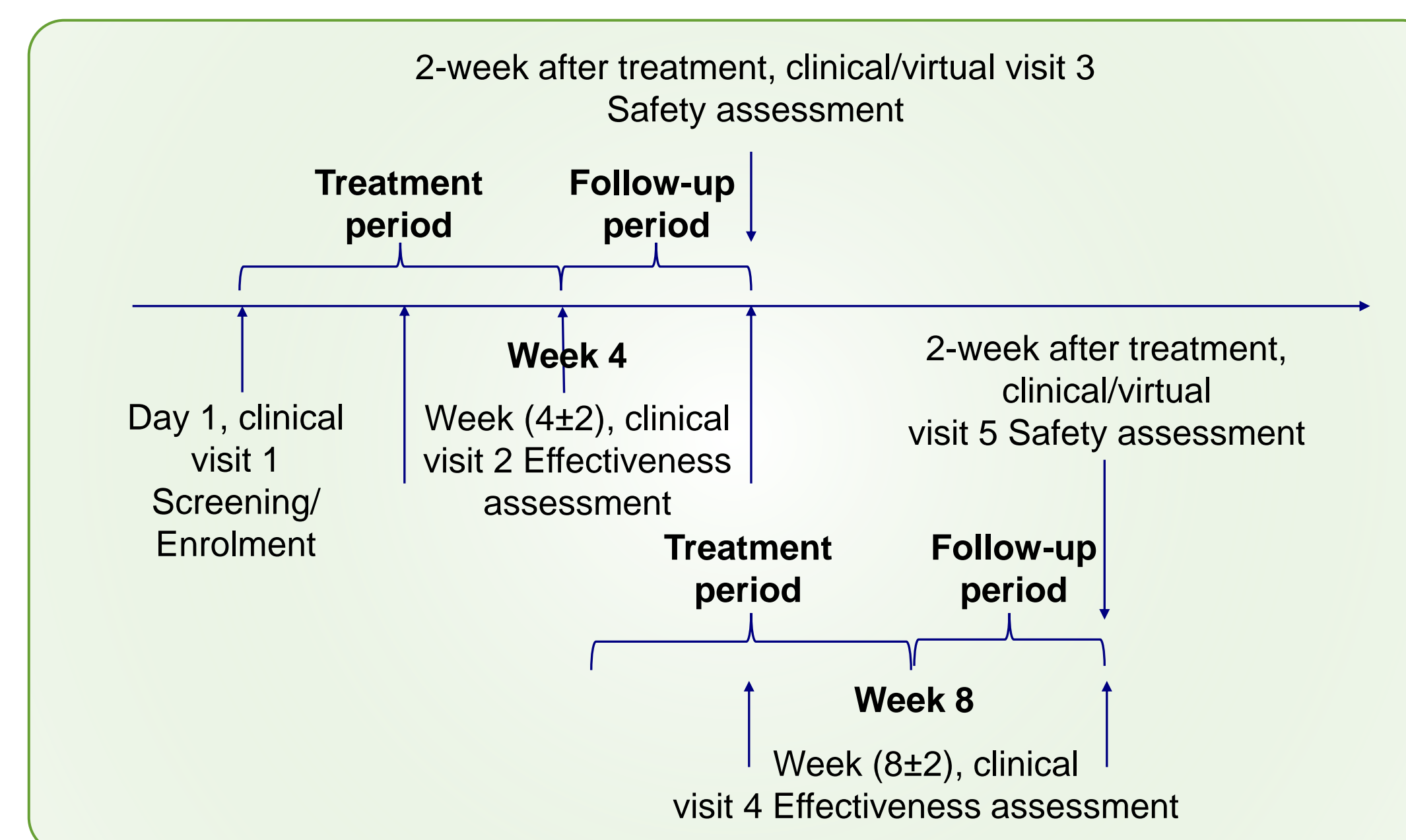
Patient Population:

Chinese patients with RE.

Treatment:

The patient population was treated with 20 mg vonoprazan orally QD for 4 weeks (8 weeks if insufficient benefit) with a 2-week safety follow-up.

Figure 1. Flow diagram of study design

Outcomes

- Effectiveness of vonoprazan in the overall population and patients ≥65 years assessed using changes from baseline to week 4 in PRO scores.
  - Sleep quality and patterns: Pittsburgh Sleep Quality Index (PSQI).
  - Quality of life: EuroQol 5-Dimension 5 level (EQ-5D-5L).
  - Health status: EQ-Visual Analogue (EQ-VAS).
  - Anxiety/depression.
  - Pain/discomfort.

  A negative difference in the PSQI score and positive differences EQ-5D-5L, EQ-VAS scores represented an improvement.

Statistical analysis

Descriptive statistics; point estimates and 95% confidence intervals (CI) for endpoints.

RESULTS

Analysis set

A total of 1796 patients were evaluated in this study; among these 250 were elderly patients (aged ≥65 years).

PRO scores

- Mean ± SD (95% CI) for change in PSQI scores from baseline and week 4 in 1360 patients was -0.7±2.31 (-0.79, -0.55). For 189 elderly patients ≥65 years, the mean ± SD difference was -0.5±2.46 (-0.90, -0.19). (Table 1).
- For 1443 patients with EQ-5D-5L scores, the mean ± SD difference was 0.029±0.0809 (0.0251, 0.0335) in the overall population while 205 elderly patients ≥65 years showed a mean ± SD of difference of 0.033±0.0845 (0.0218, 0.0451) from baseline to week-4 (Table 1).
- For 1454 patients with EQ-VAS scores, the mean ± SD difference was 4.5±11.28 (3.87, 5.03) in the overall population and 208 elderly patients ≥65 years showed a mean ± SD of difference of 4.7±12.77 (2.98, 6.47) from baseline to week-4 (Table 1).

RESULTS

Table 1: Evaluation of QoL using PRO scores in patients with reflux esophagitis after vonoprazan treatment
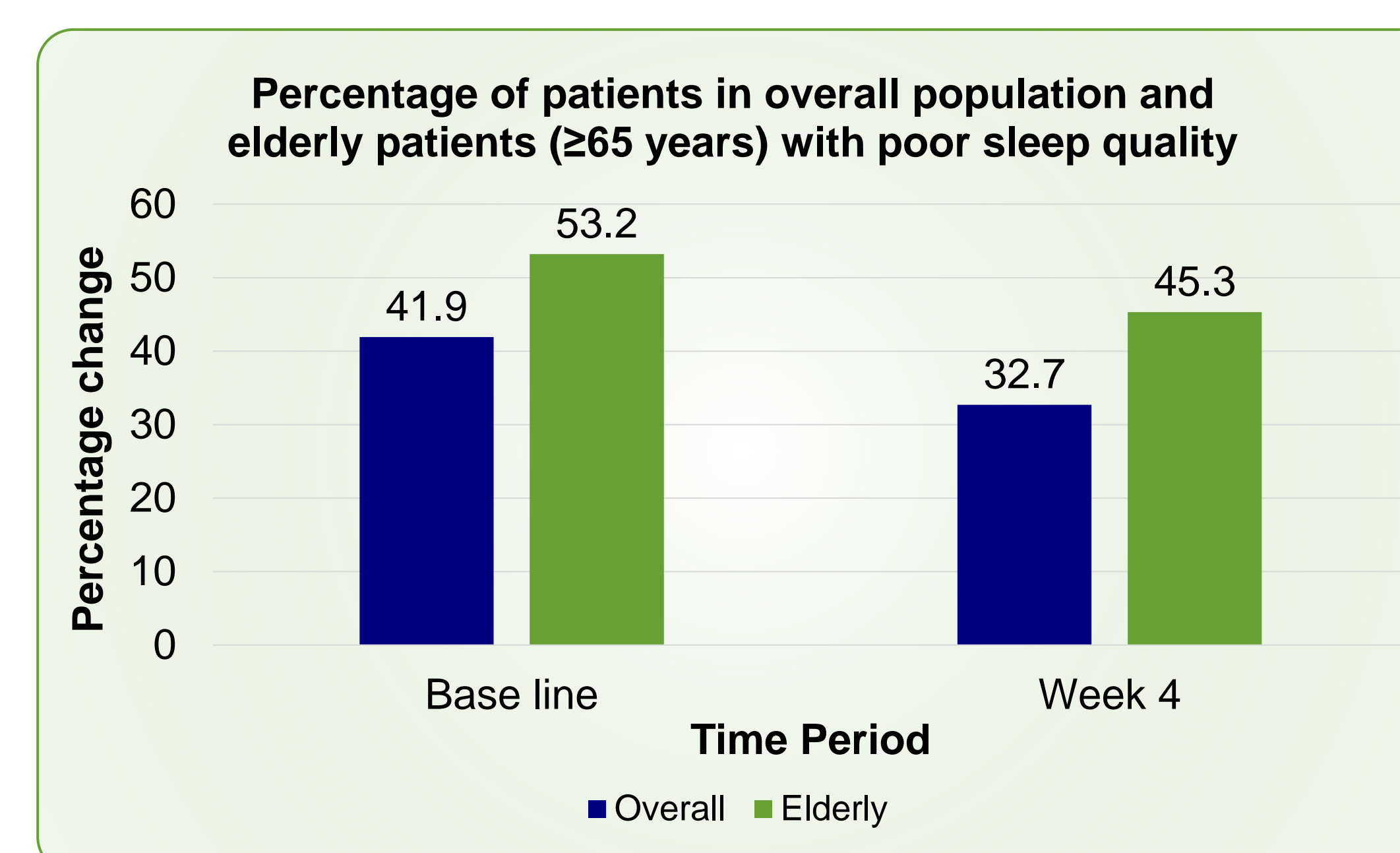
Score changes from baseline to week 4	No. of patients, n/N	Mean ± SD (95% CI)
Overall population		
PSQI	1360/1796	-0.7 ± 2.31 (-0.79, -0.55)
EQ-5D-5L	1443/1796	0.029 ± 0.0809 (0.0251, 0.0335)
EQ-VAS	1454/1796	4.5 ± 11.28 (3.87, 5.03)
Elderly patients (≥65 years)		
PSQI	189/250	-0.5 ± 2.46 (-0.90, -0.19)
EQ-5D-5L	205/250	0.033 ± 0.0845 (0.0218, 0.0451)
EQ-VAS	208/250	4.7 ± 12.77 (2.98, 6.47)

PRO, patient reported outcomes; n, subset of patients after 4 weeks of treatment; N, total number of patients assessed at baseline; S.D., standard deviation; CI, confidence interval; PSQI, Pittsburgh Sleep Quality Index; EQ-5D-5L, EuroQol-5-Dimension- 5-Level index score; EQ-VAS, EuroQol-Visual Analogue Scale

Sleep Quality

The percentage (95% CI) of patients with poor sleep quality decreased from 41.9% (39.57, 44.29) at baseline to 32.7% (30.27, 35.24) at week 4 in the overall population and from 53.2% (46.59, 59.71) to 45.3% (38.26, 52.43) in elderly patients (Figure 2).

Figure 2: Change in poor sleep quality in the overall population and elderly patients ≥65 years from baseline to week 4 after vonoprazan treatment.

Percentage of patients in overall population and elderly patients (≥65 years) with poor sleep quality

Anxiety/depression

The mean ± SD (95% CI) change from baseline to week-4 in anxiety/depression scores was -0.2±0.63 (-0.20, -0.13) in overall patients and -0.1 ±0.62 (-0.23, -0.07) in elderly patients (Figure 3a).

Pain/discomfort

The mean ± SD (95% CI) changes from baseline to week-4 in pain/discomfort score was -0.3 ± 0.77 (-0.34, -0.26) in overall patients and -0.4 ±0.83 (-0.47, -0.24) in elderly patients (Figure 3b).

RESULTS

Figure 3: Change of mean ± SD value in anxiety/depression (3a) and pain/discomfort (3b) scores in the overall population and patients ≥65 years from baseline to week 4 after vonoprazan treatment
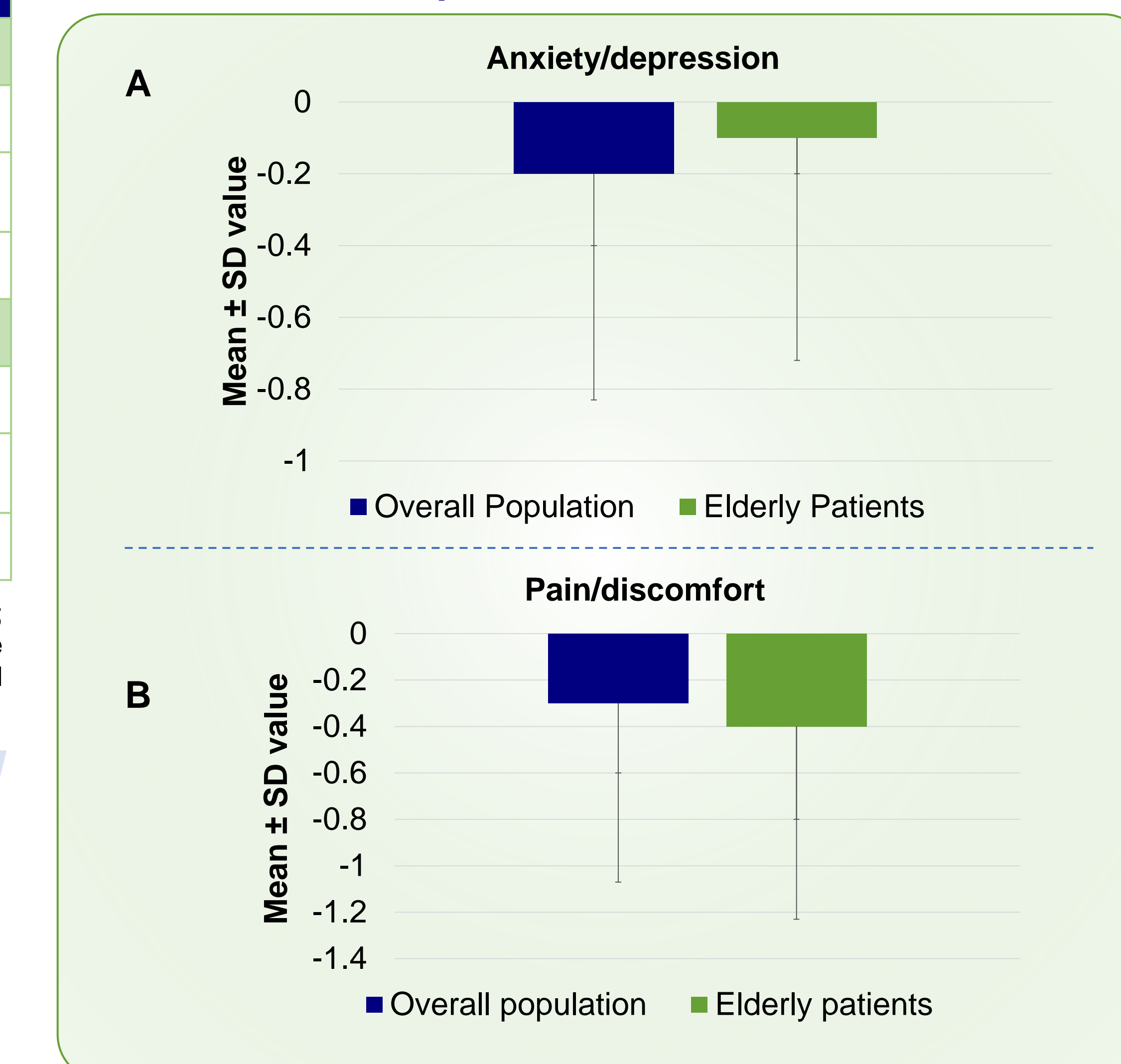
CONCLUSION

Vonoprazan treatment improved both sleep quality and quality of life in Chinese patients diagnosed with RE in real-world clinical practice

Conflicts of interest

The study was funded by Takeda China. Yinglian Xiao, Zhanxiong Xue , Zhenyu Zhang have no conflicts of interest. Qi Song, and Li Xie are employees of Takeda, and they hold Takeda stock options. Corresponding author Minhu Chen received speaker honorariums from Takeda China

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