Post Hoc Analysis of Patient and Treatment Characteristics by Vonoprazan Treatment Duration: Results From Patients With Reflux Oesophagitis in the VIEW Study

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BACKGROUND

- Reflux oesophagitis (RE) management remains challenging with various factors influencing treatment outcomes.[1]
- Vonoprazan, a novel potassium-competitive acid blocker, is approved in China as a first-line treatment for RE.[2,3]
- However, the impact of patient and treatment characteristics on the duration of vonoprazan therapy in patients with RE remains unclear.
- Understanding the factors associated with treatment duration may help optimize individualized management strategies for patients with RE.
- This post hoc analysis evaluated the influence of these factors on vonoprazan treatment duration.

OBJECTIVE

To assess the impact of baseline demographics, patient characteristics, concomitant medications, and treatment duration with previous medications on vonoprazan treatment duration in patients with RE.

METHODS

Study design:

The VIEW (NCT04501627) study is a multicenter, single-arm, prospective, real-world study in China.

Patient Population:

This post-hoc analysis included the safety analysis population, comprising Chinese patients with RE who received ≥1 dose of vonoprazan during routine care and provided safety information.

Treatment:

Patients received 20 mg vonoprazan orally once daily for 4 weeks (8 weeks for insufficient healing) and were followed up for safety for 2 weeks

Outcomes

Impact of baseline demographics, patient characteristics, concomitant medications, and treatment duration with previous medications on vonoprazan treatment duration of-

- 4 weeks
- 8 weeks

Statistical analysis

Pearson's chi-square (categorial variables) and t-test (continuous variables) was used to compare differences between the 4- and 8-week treatment duration groups.

RESULTS

Of the 3000 eligible patients, 2999 patients were enrolled in the study and 1877 patients with RE were included in the safety analysis set. One patient who did not meet the inclusion criteria was excluded from the study.

Patient baseline characteristics

- The mean (SD) age and body mass index of the patients were 49.7 (13.42) years and 24.06 (3.47) kg/m^2, respectively.
- A majority of the patients (64.4%) were male.
- A total of 18.9% were current smokers and 7.2% were former smokers.
- For Los Angeles (LA) classification, 576 (41.3%) patients had grade A reflux esophagitis, 389 (27.9%) had grade B, 85 (6.1%) had grade C and 27 (1.9%) had grade D.
- A total of 1428 patients were treated for 4-weeks, and 449 patients were treated for 8-weeks. (**Table 1**).

Table 1: Baseline summary of patients with RE (Safety Analysis Set)

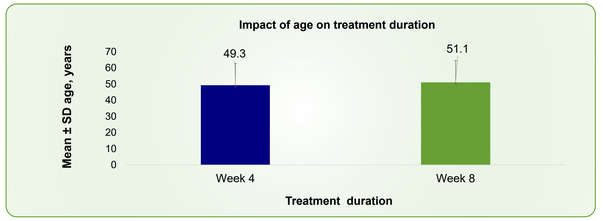
Characteristics	No. of patients, n/Nx	Overall (N=1877)
Age, years, mean (SD)	-	49.7 (13.42)
BMI, kg/m^2, mean (SD)	-	24.06 (3.47)
Gender, (%)		
Male	1208/1877	64.4
Female	669/1877	35.6
Smoking History, (%)		
Never	1387/1877	73.9
Former	136/1877	7.2
Current	354/1877	18.9
LA classification at baseline, (%)		
A	576/1396	41.3
B	389/1396	27.9
C	85/1396	6.1
D	27/1396	1.9
Oesophageal Ulceration, (%)		
Yes	238/1864	12.8
No	1626/1864	87.2
Helicobacter Pylori Status at enrolment, (%)		
Positive	236/1877	12.6
Negative	820/1877	43.7
Unknown	821/1877	43.7
Previous Treatments for RE, (%)		
PPI	509/673	75.6
H2 receptor antagonist	26/673	3.9
Gastroprokinetic agents	159/673	23.6
Other	401/673	59.6

n, subset of patients; N, Number of patients in safety analysis population for RE; RE, Reflux oesophagitis; PPI, proton pump inhibitors; S.D., standard deviation

Impact of baseline demographics

The mean ages of patients were 49.3 (13.39) years in the 4-week treatment group and 51.1 (13.44) years in the 8-week treatment group, with a statistically significant difference between groups (P = 0.011; **Figure 1**).

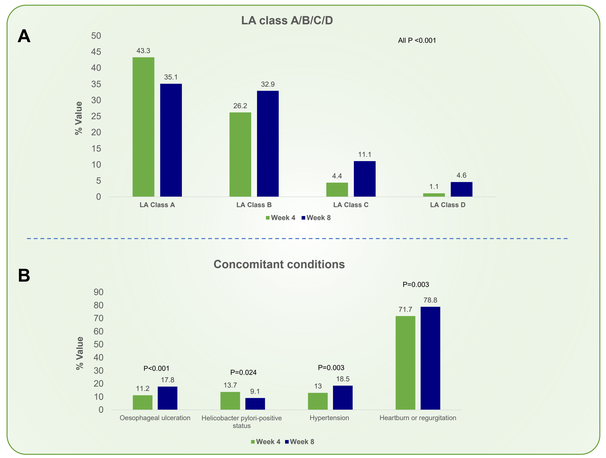
Figure 1: Impact of age on vonoprazan treatment durationz



Impact of patient characteristics

- At baseline, the distribution of LA classification in the 4-week treatment group was 43.3% for grade A, 26.2% for grade B, 4.4% for grade C, and 1.1% for grade D. In the 8-week treatment group, the corresponding proportions were 35.1%, 32.9%, 11.1%, and 4.6%, respectively. A statistically significant difference in baseline LA classification between the two groups was observed (P < 0.001; **Figure 2A**).
- Concomitant conditions at enrolment, including oesophageal ulceration (11.2% vs 17.8%, P<0.001), Helicobacter pylori-positive status (13.7% vs 9.1%, P=0.024), hypertension (13.0% vs 18.5%, P=0.003), and heartburn or regurgitation (71.7% vs 78.8%, P=0.003) also differed significantly between the 4- and 8-week treatment groups and were associated with variations in vonoprazan treatment duration (**Figure 2B**).
- The mean baseline Gastroesophageal Reflux Disease Questionnaire score was 8.3 in the 4-week group and 8.8 in the 8-week group, with a statistically significant difference between groups (P = 0.003), which also influenced treatment duration.

Figure 2: Impact of (A) LA class A/B/C/D (B) concomitant conditions on vonoprazan treatment duration



Impact of concomitant medications

Concomitant use of proton pump inhibitors (PPIs; 6.6% vs 3.6%, P=0.018) and mucosal protective agents (13.6 vs 8.7, P=0.006) also differed significantly between the 4- and 8-week groups and was associated with variations in vonoprazan treatment duration.

Impact of treatment duration with previous medications

Duration of treatment with previous medications (PPIs, H2 receptor antagonists, gastroprokinetic agents, and others) did not impact vonoprazan treatment duration between the two groups.

CONCLUSION

In patients with RE, baseline demographics, patient characteristics, and concomitant medications influenced vonoprazan treatment duration, whereas the duration of treatment with previous medications did not.

These findings highlight the importance of considering baseline patient characteristics and comorbidities when determining the optimal duration of vonoprazan therapy in real-world RE management.

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Conflicts of interest

The study was funded by Takeda (China) International Trading Co., Ltd., an affiliation of Takeda Pharmaceutical Company. Yinglian Xiao, Wensheng Pan, and Hong Xu received research funding from Takeda (China). Kailun Liang and Li Xie are Takeda employees and hold Takeda stock options. Minhu Chen received speaker honoraria from Takeda China, Xian Janssen, and AbbVie China, as well as research funding from Takeda (China).

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Abbreviations

GERD, gastroesophageal reflux disease; LA, Los Angeles; PPI, proton pump inhibitors; RE, reflux oesophagitis; SD, standard deviation