Gastrointestinal tolerability of tenapanor to treat hyperphosphatemia in patients on hemodialysis

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Background
- Hyperphosphatemia is a common complication of chronic kidney disease (CKD) stage 5D and is associated with mortality and morbidity.
- The use of phosphate binders for the treatment of patients with hyperphosphatemia is commonly associated with gastrointestinal side effects including nausea, cramps, vomiting, and weight gain.
- Tenapanor is a selective TGR5 receptor antagonist that inhibits the absorption of intestinal sodium and phosphate.

Methods
- This was a double-blind, parallel-group study with an 8-week randomized treatment period followed by a 4-week randomized placebo-controlled withdrawal period (ClinicalTrials.gov identifier: NCT02573571).
- The study was conducted in accordance with the Declaration of Helsinki at 32 sites in the USA, with all patients providing written informed consent.

Results
- Study participants
  - In total, 218 patients were randomized; 218 patients received at least one dose of study drug.
  - 104 entered the 4-week randomized treatment period and 102 completed the study (Figure 2).
- The most common reason for discontinuation of study treatment were AEs and discontinuation of study drug.

Adverse events
- A summary of the gastrointestinal AEs reported during the study is shown in Table 2.
- Most cases of diarrhea were mild or moderate in severity.
- The most common SAEs were fluid overload (n = 3) and pneumonia (n = 3) during the randomized treatment period.

Conclusions
- Tenapanor was well tolerated in patients with hyperphosphatemia undergoing hemodialysis.
- The most common AE was diarrhea.

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Figure 1. Study design

Figure 2. Patient flow diagram.

Figure 3. Bowel movement frequency (a) and stool form (b).

Table 1. Summary of adverse events.

Table 2. Gastrointestinal adverse events.

References

Disclosures
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