Poster P0787

Reduction in Gastrointestinal Visits and Portal Messaging Following Tenapanor (IBSRELA) Initiation in Patients in Community Gastrointestinal Practices

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Introduction

- Irritable bowel syndrome with constipation (IBS-C) is a chronic disorder of gut-brain interaction associated with high health care resource utilization (HCRU).[1,2]
  - Patients with IBS-C have higher HCRU than matched comparators, including patients with irritable bowel syndrome, due to more severe gastrointestinal (GI) symptoms.[2,3]
- The adoption of electronic health record (EHR) systems into United States hospitals has improved clinical practice but has also increased the burden placed on gastroenterology providers.[4,5]
  - For example, high volumes of patient-related messaging increase provider workload, which can contribute to physician burnout and may have a detrimental effect on patient care in the long-term.[5]
- An EHR study is ongoing to understand the real-world use and outcomes of IBS-C medications in community GI practices. Here, we report findings for within-patient changes in GI-related HCRU following tenapanor (IBSRELA) initiation for the treatment of IBS-C.

Methods

- This observational study used EHR data from patients treated at a large medical group of approximately 350 gastroenterology providers serving over 6 million patients across 7 states.
- Eligible patients were aged ≥18 years, had a diagnosis of IBS-C, had ≥1 visit within the 365 days before initiating tenapanor, and initiated tenapanor ≥365 days prior to the EHR data pull.
  - For the analysis of patient portal message activity, patients had to have ≥1 patient portal message in the 365 days before initiating tenapanor.
- The within-patient change in clinical encounters and portal message activity was calculated by comparing use in the 365 days before versus after tenapanor initiation.
  - Clinical encounters were defined as the total number of visits and total number of labs; portal message activity was defined as the total number of messages and total number of patient words.
- Within-patient change in clinical encounters and portal message activity was stratified by tertile of pre-tenapanor HCRU, with tertile boundaries used to categorize patients as high, moderate, and low users.

Results

Patients

- Overall, 712 patients were included in the full analysis set (**Table 1**), and 140 patients met the criteria for the analysis of patient portal messaging.

Table 1: Baseline Characteristics

	Full analysis set (N=712)
Age at first encounter, mean (SD), y	48.4 (15.3)
Sex, n (%)	
Female	612 (86.0)
Male	99 (13.9)
Unknown	1 (0.1)
Race/ethnicity, n (%)	
White	332 (46.6)
Asian	5 (0.7)
Black or African American	63 (8.8)
Multiple races	75 (10.5)
Hispanic	41 (5.8)
Other/unspecified/declined	196 (27.5)
Body mass index, mean (SD), kg/m²	26.8 (5.9)[a]
Medicare, n (%)	310 (43.7)[b]
Medicaid, n (%)	4 (0.6)[b]

[a]n=711. [b]n=709.

Reduction in Clinical Encounters Following Tenapanor Initiation

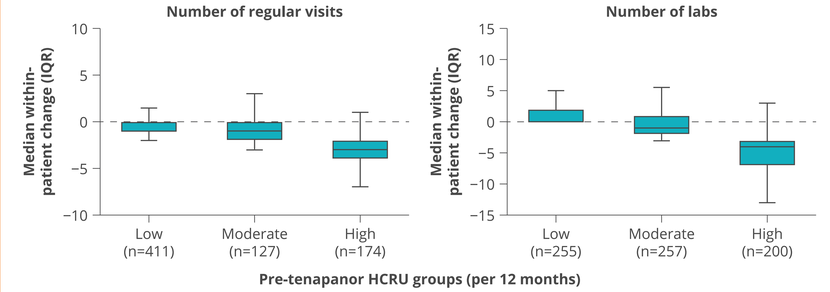
- In the full analysis set (N=712), the median within-patient change in GI visits after tenapanor initiation was −1 (quartile [Q]1: −2, Q3: 0) for regular visits and 0 (Q1: −3, Q3: 1) for labs.
- Among high users (**Table 2**), the number of regular visits and labs after tenapanor initiation reduced by a median of −3 (Q1: −4, Q3: −2) and −4 (Q1: −7, Q3: −3), respectively (**Figure 1**).

Table 2: Stratification of Patients by Total Pre-Tenapanor Clinical Encounters

Clinical encounter type	Pre-tenapanor HCRU group	N	Pre-tenapanor HCRU range (per 12 months)
Number of regular visits	High	174	4-15
	Moderate	127	3
	Low	411	1-2
Number of labs	High	200	4-34
	Moderate	257	1-3
	Low	255	0

HCRU, health care resource utilization.

Figure 1: Within-Patient Change in Clinical Encounters After Tenapanor Initiation Stratified by Tertiles of Pre-Tenapanor HCRU



HCRU, health care resource utilization; IQR, interquartile range.

Reduction in Patient Portal Messaging Following Tenapanor Initiation

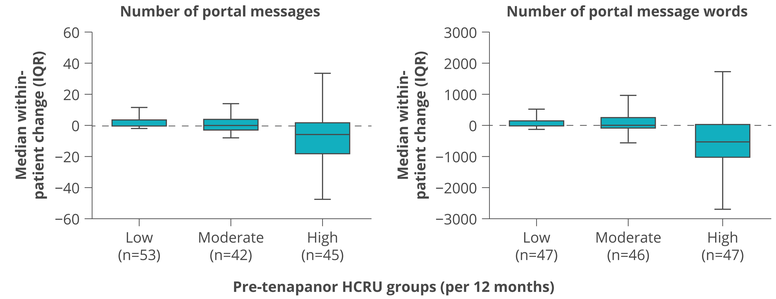
- Among patients meeting analysis criteria (N=140), the median within-patient change was −1 (Q1: −3, Q3: 3) for the number of portal messages and −38 (Q1: −257, Q3: 227) for the number of patient message words.
- Among high users (**Table 3**), the number of messages and number of words in messages after tenapanor initiation declined by a median of −6 (Q1: −19, Q3: 2) and −531 (Q1: −1059, Q3: 54), respectively (**Figure 2**).

Table 3: Stratification of Patients by Pre-Tenapanor Portal Message Activity

Measure of portal messaging	Pre-tenapanor HCRU group	N	Pre-tenapanor HCRU range (per 12 months)
Number of messages	High	45	10-61
	Moderate	42	3-9
	Low	53	1-2
Number of message words	High	47	606-5270
	Moderate	46	134-605
	Low	47	4-133

HCRU, health care resource utilization.

Figure 2: Within-Patient Change in Portal Message Activity Before and After Tenapanor Initiation, Stratified by Tertiles of Pre-Tenapanor HCRU



HCRU, health care resource utilization; IQR, interquartile range.

Limitations

- There was no method to determine medication compliance.
- The sample size for analysis of patient portal activity was small, limiting the ability to draw definitive conclusions.
- This analysis lacks a comparator group (eg, patients who initiated other IBS-C medications). As such, the within-patient change in clinical encounters cannot be appraised, nor the patient portal activity associated with tenapanor initiation in the larger context of IBS-C treatment.

Conclusions

These preliminary findings indicate that GI-related clinical encounters and patient portal message activity decreased after tenapanor initiation among patients with high pre-tenapanor HCRU in each category. This reduction in HCRU may relieve burden on providers and patients, potentially leading to cost savings.

Disclosures

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IBSRELA® (tenapanor) is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults

Important Safety Information

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

- **IBSRELA is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile rats, administration of tenapanor caused deaths presumed to be due to dehydration. *[see PI Contraindications (4), Use in Specific Populations (8.4)]*.**
- **Avoid use of IBSRELA in patients 6 years to less than 12 years of age. *[see PI Warnings and Precautions (5.1), Use in Specific Populations (8.4)]*.**
- **The safety and effectiveness of IBSRELA have not been established in pediatric patients less than 18 years of age. *[see PI Use in Specific Populations (8.4)]*.**

CONTRAINDICATIONS

IBSRELA is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.

IBSRELA is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

WARNINGS AND PRECAUTIONS

Risk of Serious Dehydration in Pediatric Patients

IBSRELA is contraindicated in patients below 6 years of age. The safety and effectiveness of IBSRELA in patients less than 18 years of age have not been established. In young juvenile rats (less than 1 week old; approximate human age equivalent of less than 2 years of age), decreased body weight and deaths occurred, presumed to be due to dehydration, following oral administration of tenapanor. There are no data available in older juvenile rats (human age equivalent 2 years to less than 12 years).

Avoid the use of IBSRELA in patients 6 years to less than 12 years of age. Although there are no data in older juvenile rats, given the deaths in younger rats and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of IBSRELA in patients 6 years to less than 12 years of age.

Diarrhea

Diarrhea was the most common adverse reaction in two randomized, double-blind, placebo-controlled trials of IBS-C. Severe diarrhea was reported in 2.5% of IBSRELA-treated patients. If severe diarrhea occurs, suspend dosing and rehydrate patient.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions in IBSRELA-treated patients (incidence ≥2% and greater than placebo) were: diarrhea (16% vs 4% placebo), abdominal distension (3% vs <1%), flatulence (3% vs 1%) and dizziness (2% vs <1%).

For additional safety information, including the Boxed Warning, please see full Prescribing Information: click here.

IBS-C, irritable bowel syndrome with constipation.

IBSRELA (tenapanor hydrochloride). Prescribing information. Ardelyx, Inc; 2025.
Available at: https://www.ibsrela-hcp.com/PI