Patient Willingness to Use ROSE-010: A Subcutaneous GLP-1 Analogue for IBS Pain Episodes

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BACKGROUND

- Although irritable bowel syndrome (IBS) is a multi-symptom disorder, abdominal pain is its defining characteristic and the principal driver of illness severity (Spiegel et al. Am J Gastro 2008;103:2536). However, there are few effective therapies for treating breakthrough abdominal pain in IBS.
- Phase II data reveal that a subcutaneously (SC) administered glucagon-like peptide 1 analogue (ROSE-010) reduces pain episode severity by up to 50% within an hour of injection vs. placebo (Hellström et al. APT 2008).
- However, it is unclear whether IBS patients would want to use a SC agent for pain, and if so, what minimum level of pain would justify use.

OBJECTIVE

- To describe the prevalence and characteristics of IBS patients who might be willing to use a SC agent for breakthrough pain.
- To compare illness severity measures and pain profiles between patients willing vs. unwilling to use ROSE-010.
- To establish the minimum level of pain, using the traditional 11-point numeric rating scale, that would trigger use of ROSE-010.

METHODS

Patients

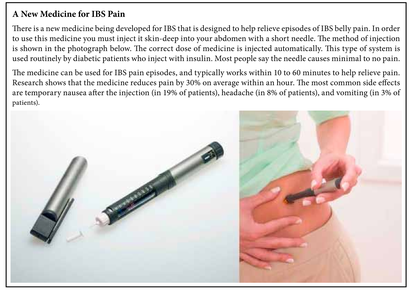
- We recruited Rome III IBS subjects from the Patient Reported Observed Outcomes and Function (PROOF) cohort, an ongoing natural history study of IBS patients from 8 geographically diverse academic and community-based U.S. centers.

METHODS (CONTINUED)

Patient Survey

- Patients first reviewed a standardized product profile (Figure 1). The profile described the indications, method of administration, side effect profile, time to peak onset, and potential symptom improvement of the medication based on published data.

Figure 1. Standardized product profile for ROSE-010.



A New Medicine for IBS Pain

There is a new medicine being developed for IBS that is designed to help relieve episodes of IBS belly pain. In order to use this medicine you must inject it skin-deep into your abdomen with a short needle. The method of injection is shown in the photograph below. The correct dose of medicine is injected automatically. This type of system is used routinely by diabetic patients who inject with insulin. Most people say the needle causes minimal to no pain.

The medicine can be used for IBS pain episodes, and typically works within 10 to 60 minutes to help relieve pain. Research shows that the medicine reduces pain by 30% on average within an hour. The most common side effects are temporary nausea after the injection (in 19% of patients), headache (in 8% of patients), and vomiting (in 3% of patients).

- After reviewing the profile, patients were asked: "Based on the information provided, and ignoring price or insurance coverage, if this medication were available how often would you use it when you have your IBS pain episodes?" Patients selected from a 5-point ordinal scale, as follows:
  - *I would never use this medication*
  - *I would rarely use this medication*
  - *I would sometimes use this medication*
  - *I would use this medication most of the time*
  - *I would always use this medication*
- Among those willing to use at least "sometimes," we asked: "On a scale from 0 (no pain) to 10 (worst imaginable pain), how severe would your IBS pain have to be in order to consider using the medication described?"

METHODS (CONTINUED)

Analyses

- We performed t-tests comparing "willing" vs. "unwilling" groups across severity metrics, including IBS-SSS, severity numeric rating scale (NRS), pain NRS, pain episode characteristics, work productivity (WPAI), & Hospital Anxiety & Depression (HAD) scale.
- We hypothesized that patients willing to use ROSE-010 would have, higher symptom severity, lower work productivity, worse psychosocial health, and more severe and frequent pain episodes compared to "unwilling" patients.

RESULTS

- Table 1 displays the characteristics of the 146 participants.

Table 1. The characteristics of the 146 participants.

Variable	Mean
Age (mean +SD)	42 +15
Gender (% Female)	83%
Race (% White / Black / Other)	82% / 12% / 6%
Education (% Professional / College / High School)	27% / 65% / 78%
Income (% <50K / 50-100K / >100K)	45% / 35% / 20%
IBS Pain Severity (10-point numeric rating scale)	4.5 +2.5
IBS Global Severity (0-20 point numeric rating scale)	11 +5
IBS-QOL Overall Score	63 +22

- Over half of the patients indicated willingness to use the agent at least "sometimes." In contrast, 24% indicated that they would "rarely" use the agent, and another 19% indicated "never."
- Among those willing to use ROSE-010, the mean severity that would trigger use of the agent was 7.8± 2.2 on the 0-10 numeric rating scale.
- Table 2 shows data for willing vs. unwilling groups.

RESULTS

Table 2. Patients "Willing" vs. "Unwilling" to use ROSE-010 Stratified by Symptomatic and Psychological Illness Severity Measures.

	Not Willing to Use (N=63)	Willing to Use (N=83)	P-Value
IBS Severity *(IBS-SSS)*	179.3	220.3	0.03
Pain Severity *(11-point NRS)*	2.0	3.5	<0.001
Pain Episode Frequency *(days per month)*	8.0	11.9	0.03
Work Presenteeism *(% of work week affected by IBS)*	26.8	38.0	0.04
Somatization *(PHQ score)*	7.9	8.3	0.67
HAD Anxiety	7.4	7.8	0.69
HAD Depression	4.4	4.3	0.97

- Patients willing to use ROSE-010 had significantly higher overall IBS symptom severity scores, higher overall pain severity, and more frequent pain episodes.
- Patients willing to use ROSE-010 reported that 38% of their workweek, on average, was disrupted by IBS symptoms. In contrast, patients unwilling to use reported that 27% of their workweek was disrupted.

CONCLUSIONS

- Over half of IBS patients in a clinical practice cohort are willing to use ROSE-010 for acute pain episodes; but pain must be severe (nearly 8/10) to justify use.
- Patients willing to use ROSE-010 exhibit more severe and frequent pain attacks compared to those unwilling to use the agent, and have a lower overall work productivity. However, willingness to use ROSE-010 is not related to anxiety, depression, or other psychological traits.
- This suggests that a SC GLP-1 agent may fulfill an unmet need for many IBS patients with impactful symptoms regardless of psychological traits.

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