Novel Agent Improves GI Function in Pain Patients

Alvimopan May Increase Spontaneous Bowel Movements in Patients Taking Opioids

	Average Increase in SBMs per Week
0.5 mg twice daily	3.5
1 mg once daily	3.5
1 mg twice daily	4.3
Placebo	1.7

Note: Based on a study of 522 patients receiving opioid treatment.
Source: Dr. Webster

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SAN ANTONIO — Alvimopan is effective in relieving gastrointestinal adverse events associated with opioid administration, according to preliminary data.

"We were able to demonstrate that alvimopan, a μ-opioid receptor antagonist that is taken orally, was able to increase bowel function significantly," lead investigator Dr. Lynn Webster reported in a poster presentation at the annual meeting of the American Pain Society Meeting. "At several different doses, the side effects were similar to what was seen with placebo."

Patients using opioids to treat chronic moderate to severe pain often develop gastrointestinal adverse events, including constipation, abdominal pain and discomfort, and bloating. These side effects can prevent some patients from adequately managing their pain.

"There is a very significant need for this type of agent," said Dr. Webster, medical director of a group practice in Salt Lake City. "About 50% of my patients have a significant bowel dysfunction from opioid use, and it sometimes limits the amount of opioids that they can be given."

The problem can be life threatening, causing complications such as bowel perforation in some patients, he added.

The efficacy of alvimopan was evaluated in a 6-week study of 522 patients receiving opioid treatment for persistent noncancer pain. The phase IIb double-blind design randomized patients to 0.5 mg alvimopan twice daily, 1 mg alvimopan once daily, 1 mg alvimopan twice daily, or placebo.

Overall, 40% of the patients who received alvimopan reported moderate to substantial improvement in constipation, vs. 14% with placebo.

Patients in all of the groups reported an average frequency of one spontaneous bowel movement (SBM) per week during the baseline period. The average increase in SBMs per week during the treatment period was about 3.5 in the two daily alvimopan groups, and 4.3 in the twice daily group; the increases were significantly greater than the 1.7 increase seen among patients given placebo. (See chart.) The increase in SBMs was apparent within the first week of the study, was sustained throughout the entire treatment period, and returned toward baseline when alvimopan was discontinued.

Patients on active therapy also reported improvements in straining, stool consistency, completeness of evacuation, and abdominal pain and bloating, compared with placebo. Overall, 40% of the patients who received alvimopan reported moderate to substantial improvement in constipation, vs. 14% with placebo. Patients using alvimopan also reported a significantly lower need for rescue laxatives.

The most common adverse events reported in the trial were abdominal pain, nausea, and diarrhea, occurring in 30%-43% of patients on active therapy and 36% of those on placebo. Overall, withdrawal rates for adverse events were 13% or lower across all treatment groups. The best benefit-to-risk profile was seen with the 0.5-mg twice-daily dose.

"The important thing is that we demonstrated efficacy with a low risk of adverse events," Dr. Webster said. "Any opportunity that we have to restore as much normal bowel function as possible, with very little side effect and risk, presents a great opportunity." ■

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