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Targeted antibiotic drug safest among recommended treatments for irritable bowel disease

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Among the most commonly used treatments for irritable bowel syndrome – which affects as many as 20 percent of the United States population – a targeted antibiotic was shown to be the safest in a new study by Cedars-Sinai researchers, based on an analysis of 26 large-scale clinical trials.

The study, for presentation at the American College of Gastroenterology annual meeting in Washington, D.C., examined drug interventions for IBS deemed to be of merit by a task force of the group . The study compared the therapies based on "number needed to harm statistics" from large clinical trials. In evaluating a drug's effectiveness, two common measures are the number needed to treat (the average number of patients who must take a therapy before one is treated successfully) and the number needed to harm (how many patients must be treated before the adverse effects of a therapy are bad enough that one patient drops the medication).

"For patients who suffer from irritable bowel syndrome, historically effective treatment options have been very scarce," said Mark Pimentel, MD, director of the G.I. Motility Program at Cedars-Sinai Medical Center and a lead author on the study. "Unfortunately, many of the treatments approved for IBS cause intolerable complications for many patients. This underscores the need for us to continue to seek new therapies for this disease, which dramatically harms quality of life for

millions of people."

The study looked at the most common and highly rated treatments for the condition. Three of these treatments are for diarrhea-predominant IBS: tricyclic antidepressants; alosetron – a drug that slows movement of stool in the gut; and rifaximin, an antibiotic absorbed only in the gut. The difference among these drugs was striking. For tricyclic inhibitors, the number needed to harm was 18.3, while the number needed to harm for alosetron was 19.4. For rifaximin, the number needed to harm was 8,971.

The study also found that for every 2.3 and 2.6 patients who benefitted from tricyclic inhibitors and alosetron respectively, one patient was harmed by the study medication and had to withdraw. For rifaximin, this number was 897.

"This further validates previous research we've done on rifaximin as a safe and effective treatment for IBS," Pimentel said. "Now, not only have our previous clinical studies shown that this selectively absorbed antibiotic is the first treatment for IBS patients in which patients continue to have relief from their symptoms after stopping the drug – compared to other available treatments for the condition, it statistically has caused fewer adverse side effects."

In an article published earlier this year in the *New England Journal of Medicine*, the ground-breaking therapy developed at Cedars-Sinai found through two double-blind trials that patients who suffered from diarrhea prominent IBS reported relief from bloating, less abdominal pain and improved stool consistency for up to 10 weeks. While the concept of bacteria playing a key role in IBS was controversial when first unveiled a decade ago, this research confirms that bacteria in the gut trigger the symptoms of the chronic condition, affecting an estimated 30 million people in the United States.

Rifaximin is marketed by Salix Pharmaceuticals Inc. Pimentel discovered the use of rifaximin for IBS, and Cedars-Sinai holds patent rights to this discovery and has licensed rights to the invention to Salix. Dr. Pimentel is a consultant to Salix Inc, and serves on its scientific advisory board.

Provided by Cedars-Sinai Medical Center