

# Doctor-Patient Dialogue Helps Patients With IBS

*Educational strategy offers a low-cost, effective intervention that can reduce global symptoms.*

BY BETSY BATES  
Los Angeles Bureau

LOS ANGELES — An educational tool kit designed to improve patient-physician interactions during visits for irritable bowel syndrome had a greater impact on global symptom relief than did any medication ever studied for the enigmatic disorder.

Dr. Brennan M. Spiegel and associates at the University of California, Los Angeles, tested the tool kit in a randomized study of 73 patients with irritable bowel syndrome (IBS) symptoms who attended the gastrointestinal disease catchment clinic for the VA Greater Los Angeles Health Care System.

Follow-up surveys 3 months later found that patients assigned to the physician-patient intervention group were far more likely than were those who received standard care to say they had achieved relief of their global symptoms (20 of 36 patients, or 56%, compared with 5 of 34 patients, or 15%).

The intervention effect size of 0.75 “exceeds the largest effect size demonstrated in pharmaceutical

studies for IBS,” Dr. Spiegel said at the annual Digestive Disease Week.

For example, studies of alosetron using similar outcome measures had effect sizes between 0.2 and 0.5, he said.

“This does not mean by any means that these agents are not effective. It does suggest that medical therapy alone may be suboptimal if it is not delivered in the context of a supportive and informative physician-patient interaction,” he said.

The multifactorial intervention consisted of a five-part tool kit that included:

- ▶ A waiting room questionnaire to document the patient’s primary concerns, fears, and opinions about what might be causing IBS symptoms.

- ▶ A laminated flash card for the physician that includes key components of an effective discussion of IBS, including reminders to ask about psychosocial elements of the disease, descriptions of IBS in lay language, and the fact that IBS is not a life-threatening disease.

- ▶ A worksheet and diagram of the brain and gut that the physician could use to depict a simple explanation of the complex neural circuitry linking the two.

- ▶ A multimedia patient educational kit, including a self-empowerment video, an explanation of the brain-gut axis in lay language, information about support groups, a dietary card, and educational materials about IBS from the National Institutes of Health.

▶ A letter, sent 1 month following the office visit, asking the patient, “How are you doing?” and providing information about how to contact the physician if symptoms had not improved. This correspondence also included more educational information about IBS.

Physicians were free to use or ignore the patient’s questionnaire, the flash card, and worksheet during the office visit; however, most found that it actually “streamlined” the visit, Dr. Spiegel said.

Similarly, patients could read or dispose of the educational materials provided. Some told investigators that they found the worksheet very important, while others primarily relied on the diet cards they found in the take-home educational kit.

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Whatever elements did the trick, the intervention clearly had an impact on patients, with significant differences seen in global IBS symptoms, satisfaction, and perceptions of physicians’ interpersonal skills.

Ironically, the same physicians saw IBS patients assigned to the intervention group or to usual care.

When independent observers assessed physicians’ notes from the visits, they found “very large differences” between the intervention and standard care groups in terms of observations concerning patients’ quality of life and extraintestinal symptoms such as anxiety or depression. None of the physician notes documenting visits with control group patients mentioned patients’ fears and concerns or disease education efforts, while these elements appeared in their notes regarding 23% and 54% of intervention patient visits, respectively.

Dr. Spiegel prefaced the report on his findings by acknowledging the deep frustration many physicians feel in dealing with patients with IBS, since the disease is common and expensive, symptom expression is heterogeneous, the disease model is incomplete, and highly effective treatment options are scarce.

This frustration can spill over into office visits that leave neither party satisfied.

“Unfortunately, data from our group and others demonstrate that there is a disconnect, oftentimes, between physicians and patients,” he said. “Patients often feel uninformed after they have left the office and physicians often do a poor job of predicting patients’ severity when patients and physicians fill out the same questionnaire.”

The low-cost intervention, which will now be further tested, may help to bridge gaps in communication, fostering the physician/patient relationship as a cornerstone of treatment of IBS, Dr. Spiegel said. ■

# Tegaserod Users Show Increased Work Productivity at 6 Months

BY DOUG BRUNK  
San Diego Bureau

LOS ANGELES — After 6 months of treatment with tegaserod, patients with irritable bowel syndrome increased their work productivity by an average of more than 3 hours per week compared with those who did not take the drug.

Tegaserod users also showed a significant decrease in daily activity impairment compared with those who did not take the

drug, Dr. Pierre Paré reported in a poster session at the annual Digestive Disease Week.

“We’ve known for a long time that the efficacy of this drug is demonstrated,” Dr. Paré, of the division of gastroenterology at St.-Sacrement Hospital, Quebec City, said in an interview. But this marks the first study of IBS patients in a usual care setting to show that tegaserod positively affects work productivity and daily activities.

He and his associates enrolled 1,372 patients with IBS symptoms from 147 medical practice sites across Canada. Most were family practice sites.

The researchers collected clinical and patient-reported outcomes at baseline and at months 1, 3, and 6. They used the Work Productivity and Activity Questionnaire (WPAI) for IBS to measure work activity. This questionnaire measures absenteeism, presenteeism, work productivity loss, and activity impairment resulting from IBS symptoms.

Dr. Paré reported that the mean age of

the patients was 46 years, the mean length of disease duration was 12 years, and most of the patients (86%) were female.

Of the entire group, 360 patients were tegaserod users and 1,012 were not. At baseline, a similar portion of patients in each group was employed (61% of tegaserod users vs. 60% of nonusers).

By month 6, tegaserod users showed larger but nonsignificant improvements compared with nonusers on these aspects of the WPAI: absenteeism (3%), presenteeism (8%), and overall productivity impairment (8%). However, tegaserod users did show a significant improvement on the WPAI component of daily activity impairment (12%) compared with nonusers.

Using a 40-hour work week as an average, the researchers estimated that tegaserod users reduced productivity loss by an average of 3.3 hours per week compared with nonusers. In Canada, this translates into a societal savings of about \$65 per tegaserod user per week, Dr. Paré said. In the United States, he estimated that the savings would be about \$53 per tegaserod user per week.

A key limitation of the study, he added, was its nonrandomized design. Also, “we don’t have data on outcome of clinical symptoms,” he said.

Year-long follow-up data on these patients should be available soon.

The study, which earned a “poster of distinction” designation from the meeting organizers, was funded by Novartis Pharma AG in Basel, Switzerland. ■



**Tegaserod users had a significant decrease in daily activity impairment compared with nonusers.**

DR. PARÉ

# Risk of Ischemic Colitis Increases With Irritable Bowel, Constipation

LOS ANGELES — Patients with irritable bowel syndrome are eight times as likely as other patients to develop ischemic colitis, according to a database study presented in poster form at the annual Digestive Disease Week.

Constipation is another risk factor, conferring a 2.6-fold increased risk of ischemic colitis, reported Mark Cziraky, Pharm.D., vice president of HealthCore Inc., a Wilmington, Del.-based research firm.

The study was funded and conducted on behalf of Novartis Pharmaceuticals Corp., manufacturer of several drugs for irritable bowel syndrome (IBS) and constipation.

Dr. Cziraky and his associates identified 100,143 patients with newly diagnosed IBS in the HealthCore Managed Care Database, which contains medical records for 12 million people. They matched these patients by age and gender to 100,143 controls who saw a physician for a reason other than IBS during the study period from January 2000 to February 2005. The same database also was used to identify 81,399

patients with newly diagnosed constipation and age- and gender-matched controls.

During a median follow-up time of about 18 months, there were 167 cases of ischemic colitis among the IBS patients, compared with 77 among the matched controls (90.37 cases per 100,000 patient-years, vs. 41.47 cases per 100,000 patient-years). In a multivariate model, the relative risk of ischemic colitis was 8.16 for the IBS patients, compared with the controls.

In the constipation group, there were 199 cases of ischemic colitis, compared with 64 cases in matched controls (80.44 cases per 100,000 patient-years, vs. 43.03 cases per 100,000 patient-years). In the multivariate model, the relative risk of ischemic colitis was 2.6 for the constipation patients, compared with the controls.

When researchers examined 1-year follow-up data, the data supported “an even stronger relationship” between IBS or constipation and ischemic colitis, the poster concluded.

—Betsy Bates