# Gastroenterology & Endoscopy News

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## Fundoplication, PPIs Face Off at One Year

By Ted Bosworth

LOS ANGELES—A new randomized study appears to have reestablished laparoscopic Nissen fundoplication as the gold standard for the treatment of gastroesophageal reflux disease (GERD).

In this rigorously controlled trial, symptom control and outcome after one year on medical therapy with continuous proton pump inhibitors (PPIs) was good, but surgery, performed by experienced surgeons, was better. These data, presented in May at the 2006 Digestive Disease Week meeting, refute several previous reports in which surgery

see Antireflux Therapy, page 28

## Biofeedback Therapy Gaining Momentum

By Christina Frangou

Biofeedback is getting a big boost, thanks to new research showing that this nonpharmacologic treatment has major potential as a therapy for dyssynergic defecation, constipation and incontinence.

"The clear message is that this is not voodoo," said Satish S. C. Rao, MD, PhD, Professor of Medicine, University of Iowa College of Medicine, Iowa City, and author of some of the new research. "Biofeedback is no longer something that's experimental. If this is done well

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## As Demand for Bariatric Surgery Rises, Gastroenterologists Called to Action

By Christina Frangou

The American Gastroenterological Association (AGA) wants gastroenterologists to assume a larger role in treating bariatric surgery patients—but is also warning them to proceed with caution.

Writing in the March issue of *Gastroenterology*, Samuel Klein, MD, Associate Editor for Nutrition, said that gastroenterologists should develop stronger clinical and research partnerships with bariatric surgeons (Klein S. *Gastroenterology* 2006;130:630).

However, he cautioned readers about the "dark side of bariatric surgery," evidenced by studies showing high rates of perioperative mortality and postoperative rehospitalization among patients treated at institutions with lower-than-average volumes. Gastroenterologists can help keep complications and deaths to a minimum by making sure that patients are treated by experienced surgeons operating within established programs, he advised.

"Gastroenterologists need to know when to refer patients for bariatric surgery, who are the skilled surgeons, and where are the experienced centers," wrote Dr. Klein, Director of the Center for Human Nutrition, Washington University School of Medicine, St. Louis.

Common sense advice—"like mothers and apple

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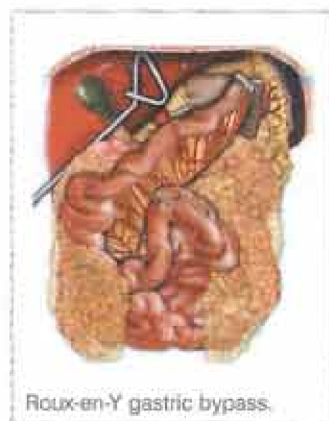
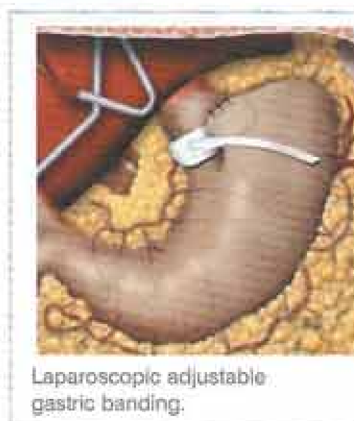
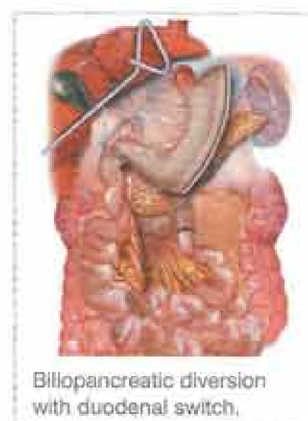

Roux-en-Y gastric bypass.


Laparoscopic adjustable gastric banding.


Biliopancreatic diversion with duodenal switch.

Illustrations courtesy of the American Society for Bariatric Surgery. Copyright © 2005 Dallel/Schauer.

## Massachusetts Pilots Healthcare Reform

### *Will the Nation Follow Suit?*

By Monica J. Smith

On April 4, 2006, the Massachusetts House and Senate voted to approve legislation that will provide healthcare coverage to approximately 95% of the 500,000 state residents currently without health insurance—if all goes as planned.

Although the plan has its critics, many physicians and others see it as a bold step toward reforming U.S. healthcare.

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PRODUCT ANNOUNCEMENT

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**OsmoPrep Tablets**

for cleansing of the colon as a preparation for colonoscopy are now available from Salix Pharmaceuticals, Inc.

## Biofeedback

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by someone who is adequately trained, biofeedback is an effective strategy."

Among the recent findings:

- Patients who undergo biofeedback therapy experience dramatically greater relief from symptoms of dyssynergic defecation than do patients given a standard therapy of diet, exercise and laxatives (Rao S et al. *Am J Gastroenterol* 2005;100[suppl 9]:S150 [Abstract 386]).
- Biofeedback alleviates the symptoms of anorectal dysfunction in patients with solitary rectal ulcer syndrome, which include excessive straining, the need for digital disimpaction, rectal hypersensitivity, dyssynergic defecation and prolonged evacuation (Rao S et al. *Am J Gastroenterol* 2006;101:613-618).
- Five biofeedback sessions are more effective than the continuous use of polyethylene glycol for treating pelvic floor dyssynergia, with benefits lasting at least two years after the training

## What is Biofeedback Therapy?

By Christina Frangou

Biofeedback is a technique used to train a patient's mind to control the way their body works. It is the most studied mind-body therapy for gastrointestinal disorders.

Biofeedback therapy takes place in two parts. To start, patients undergo a painless series of sensory tests using electric monitoring equipment. The tests measure changes in bodily functions that, in general, most people are not aware of, such as blood pressure, heart rate, skin temperature, and muscle and nerve tension in the pelvic floor. Therapists use the "biofeedback" from the tests to identify abnormalities in a patient's bodily functions and use that information to educate patients about how to correct their bodies.

Trained therapists—including physicians, nurses, and physical or occupational therapists—teach patients strengthening exercises or relaxation techniques that can be performed to reduce their symptoms. The sessions vary in number, length and frequency, and can take place in a doctor's office or at the patient's home. Patients with gastrointestinal disorders often undergo six to eight treatment sessions over a three-month period.

According to the International Foundation for Functional Gastrointestinal Disorders, practice is the key to improvement with biofeedback: "Repetition of the correct patterns and applications of these patterns to everyday situations is critical to reestablishing bowel control" (accessed on June 8, 2006 at www.aboutconstipation.org/biofeedback.html).

Biofeedback specialists caution that the success of the therapy often depends on the skills of the biofeedback therapist and the techniques used to carry out training.

"Biofeedback is not as easy as popping a pill. People need to be adequately trained. It requires motivation. It is labor-intensive. But, it's extremely effective when done well," said Satish S. C. Rao, MD, PhD, Professor of Medicine, University of Iowa College of Medicine, Iowa City, and author of several studies on biofeedback.

Notably, biofeedback training is more expensive than laxatives in short-term studies and is not widely available.

'The clear message is that this is not voodoo. Biofeedback is no longer something that's experimental. If this is done well by someone who is adequately trained, biofeedback is an effective strategy.'

—*Satish S. C. Rao, MD*

sessions. Italian investigators concluded that biofeedback should become the treatment of choice for this type of constipation (Chiarioni G et al. *Gastroenterology* 2006;130:657-664). In addition, an American study showed that biofeedback is superior to diazepam and placebo as a treatment for patients with pelvic floor dyssynergia–type constipation (Heymen S et al. Randomized controlled trial [RCT] shows biofeedback to be superior to alternative treatments for patients with pelvic floor dyssynergia-type constipation [PFD]. Presented at: 70th Annual Meeting of the American College of Gastroenterology; November 1, 2005; Honolulu, Hawaii. Paper 43).

- Individuals with depression benefited significantly from biofeedback to control their urinary incontinence, even more than patients without depression (Tadic SD et al. Presented at: Annual Meeting of the American Geriatrics Society; May 3-7, 2006; Chicago, Illinois. Abstract 50).

Biofeedback is used in a number of medical specialties, but in none more than gastroenterology. Biofeedback has been used to treat anal and rectal disorders for 30 years, but it has never been fully accepted by the medical community or accepted for insurance coverage.

Supporters of biofeedback hope that insurance coverage will soon be initiated, thanks to the growing evidence of its therapeutic impact.

"These studies may contribute to that changing. We certainly hope that it will," said Steve Heymen, MS, Instructor in Medicine, University of North Carolina School of Medicine, and Director of Biofeedback Services, UNC Center for Functional GI and Motility Disorders, Chapel Hill, N.C.

In the Spring 2006 edition of the journal *Biofeedback* (accessed on June 8, 2006 at www.aapb.org/files/public/BIOF3401-Palsson.pdf), Mr. Heymen and a colleague, Olafur S. Palsson, PsyD, Clinical Associate Professor of Medicine, Division of Gastroenterology and Hepatology, University of North Carolina School of Medicine, wrote that data supporting biofeedback for the treatment of gastrointestinal disease is finally achieving "critical mass."

"Biofeedback is proving its value like never before," they wrote. "Researchers are

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## Biofeedback

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now recognizing and systematically plugging the holes in the body of evidence that allow conclusive decisions about the value of these specialized applications of biofeedback."

The authors called the recent studies among the "best designed and most important to date."

### Dyssynergic Defecation

In a randomized trial to evaluate biofeedback therapy for dyssynergic defection, Dr. Rao and colleagues found that anorectal and colonic function, and bowel satisfaction, improved significantly in patients who received biofeedback therapy (Rao S et al. *Am J Gastroenterol* 2005;100-[suppl 9]:S150 [Abstract 386]). The improvements lasted at least one year after the biofeedback sessions were completed.

Of the 44 patients in the study group, 21 underwent biofeedback therapy with manometrically assisted pelvic relaxation, coordination and stimulated defecation training, and 23 received the standard therapy of diet, exercise and laxatives. The patients who received standard therapy had comparatively poor results, with a 46% failure rate and little change in bowel function. In comparison, the biofeedback group had normalized defecation patterns, an increased defecation index, and improvements in balloon expulsion, colonic transit and bowel satisfaction.

"Biofeedback is more effective for managing dyssynergia," said Dr. Rao, who presented the findings at the 2005 annual meeting of the American College of Gastroenterology (ACG). Dr. Rao received an ACG auxiliary award for his research.

### Solitary Rectal Ulcer Syndrome

A second study by Dr. Rao's group showed that most patients with solitary rectal ulcer syndrome experienced symptom relief and improved manometric findings with significant healing after receiving biofeedback therapy (Rao S et al. *Am J Gastroenterol* 2006;101:613-618).

In the 11 patients studied, stool frequency dropped from 14 to 10 per week ($P<0.05$), and global satisfaction with bowel habit improved in all patients (score based on the Visual Analogue Scale). The percentage of patients with blood in their stools fell from 82% to 36%, while the percentage with mucus in their stools dropped from 54% to 9%.

"Because [biofeedback therapy] is noninvasive and appears to correct some of the underlying pathophysiologic dysfunction, it may be considered in the routine management of patients with [solitary rectal ulcer syndrome], particularly those whose condition is refractory to medical therapy," the investigators wrote.

However, Dr. Rao stressed that the jury is still out on the long-term benefits of biofeedback for anorectal disorders.

"We have to follow these patients meticulously before we know that these results will hold up."

Carol A. Burke, MD, Director of the Center for Colon Polyps and Cancer, The Cleveland Clinic Foundation, said the improvements could wane over time.

Biofeedback is already the treatment of choice for many common types of fecal incontinence. Preliminary studies in the early 1990s suggested that biofeedback also might become a preferred method of treatment for patients with constipation and several anorectal disorders, but the studies were never followed up with large, well-designed trials.

In the last year, however, "several new studies have reached the finish line," according to Mr. Heymen.

### Pelvic Floor Dyssynergia

This spring, a group of Italian gastroenterologists called for biofeedback to become the "treatment of choice" for patients with pelvic floor dyssynergia, a type of constipation marked by severe contraction of the pelvic floor muscles after defecation (Chiarioni G et al. *Gastroenterology* 2006;130:657-664). They showed in a randomized study that

five 30-minute biofeedback sessions were substantially more effective than the continuous use of polyethylene glycol for treating pelvic floor dyssynergia. Eighty percent of the patients showed reductions in straining, incomplete evacuation, anorectal blockage, medication use and abdominal pain that lasted at least two years after they finished the sessions.

"By contrast, laxative treatment was relatively ineffective, was poorly tolerated when the dose was increased and required continuous treatment," the researchers noted.

Researchers from the University of North Carolina at Chapel Hill reported similar findings (Heymen S et al. Randomized controlled trial [RCT] shows biofeedback to be superior to alternative treatments for patients with pelvic floor dyssynergia-type constipation [PFD]. Presented at: 70th Annual Meeting of the American College of Gastroenterology; November 1, 2005; Honolulu, Hawaii. Paper 43). In the randomized study comparing biofeedback, diazepam and placebo, the researchers reported success rates of 70% for biofeedback, 38% for placebo and 23% for diazepam. All patients in the study were trained to perform pelvic floor exercises.

"This study provides definitive support for the efficacy of biofeedback for pelvic floor dyssynergia," said Mr. Heymen.

### Urinary Incontinence

A study presented in May at the annual meeting of the American Geriatrics Society showed that patients with urinary incontinence and depression responded better to biofeedback therapy than did nondepressed patients with urinary incontinence (Tadic SD et al. Presented at: Annual Meeting of the American Geriatrics Society; May 3-7, 2006; Chicago, Illinois. Abstract 50). In this study, biofeedback—which is recommended as a first line treatment for urinary incontinence—significantly alleviated physiologic and psychological symptoms of urinary incontinence ($P<0.0001$ for both), as well as depression in the patients with depression ($P<0.01$). The researchers said the intervention could have a significant impact on the quality of life of patients with depression. ▲