Presumed IBS May Be Missed Pelvic Floor Dysfunction

**By Timothy F. Kirn**
Sacramento Bureau

CHICAGO — Many individuals diagnosed with irritable bowel syndrome could actually have pelvic floor dysfunction, a condition that can be much more remediable, according to a study conducted at the Mayo Clinic.

Considerable overlap exists in the symptoms of pelvic floor dysfunction and irritable bowel syndrome (IBS), particularly constipation-dominant irritable bowel syndrome, even though the Rome diagnostic criteria for functional bowel disorders considers the two distinctly separate entities. Christopher N. Andrews, M.D., the main investigator of the study, said in a poster presentation at the annual Digestive Disease Week.

The study showed that few patients who present with symptoms of straining, lumpy or hard stools, or a sensation of incomplete evacuation get a pelvic floor work-up as they should, because those with pelvic floor dysfunction probably could be helped by biofeedback training of the pelvic floor muscles. Median age was in the mid-50s for all three arms of the 6-week study. The poster report on the study included data on a total of 195 patients.

One group of 94 patients started on a 37.5 mg daily dose of venlafaxine, which increased after 1 week to 75 mg. A second group of 94 patients received a single 400-mg dose of MPA. A third group took placebo.

Safety was the big unanswered question. The concern is whether MPA interferes with hormonal therapies such as tamoxifen.

**Black Cohosh Junkie’s Phase II Trial**

Black cohosh, a popular herbal remedy, failed to reduce hot flashes in a randomized, double-blind, placebo-controlled, phase III crossover trial presented in another poster at the meeting.

Barbara Pockaj, M.D., and her colleagues reported that the average decrease in hot flash scores was larger in placebo users (27%) than those in women taking 20 mg of black cohosh daily (20%).

At the end of the 9-week study, 36 (37%) of the 97 patients completing the study preferred placebo, 31 patients (32%) favored black cohosh, and 30 patients (30%) had no preference.

The other 19 patients evaluated in the study were listed as missing. The study included breast cancer patients and women with a perceived risk of breast cancer.

Toxicity results gave a slight edge to black cohosh, with no adverse events reported by 87% of patients on the herbal remedy and 77% on placebo.

None of the findings reached statistical significance. Dr. Pockaj of the Mayo Clinic in Scottsdale, Ariz., said in an interview.

“Based on this, I see no reason to take black cohosh,” Dr. Pockaj said. “It has no effect at all, not even a suggestion.”

Black cohosh is the leading hot flash treatment in Germany, said Dr. Loibl, whose German Breast Group study showed venlafaxine to be effective for hot flashes. “I am very happy that this trial has been done finally, because it shows it [black cohosh] has no effect,” she told this newspaper.

Nonetheless, she predicted that physicians would continue to recommend the herbal remedy. Venlafaxine is not approved for hot flashes, whereas black cohosh is available over the counter, Dr. Loibl noted.

**Effexor Eases Hot Flashes in Breast Ca Patients**

**Drug is more effective than clomiphene, but does not match a single dose of medroxyprogesterone acetate.**

**By Jane Salodof McNeil**
Southwest Bureau

ORLANDO, Fla. — Venlafaxine controls hot flashes more effectively than clomiphene, but not as well as a single dose of medroxyprogesterone acetate, according to a trial organized by the German Breast Group, venlafaxine reduced frequency of hot flashes by 62% and severity by 67% in breast cancer patients. Clomiphene reduced frequency by 22% and severity by 48%, reported Sibylle Loibl, M.D.

In a North Central Cancer Treatment Group trial, venlafaxine reduced hot flash frequency by 52% and median hot flash scores by 77% in the first 185 patients evaluated. A single 400-mg dose of medroxyprogesterone (MPA, Depo-Provera) achieved a 57% drop in frequency and reduced median hot flash scores by 88%, reported Charles L. Loibl, M.D.

At the Mayo Clinic, Rochester, Minn., said in an interview. “Whether is has a small effect to give,” Dr. Loprinzi, an oncologist at the Mayo Clinic, Rochester, Minn., said in an interview. “Whether or not it has a small effect to give,” Dr. Loprinzi, an oncologist at the Mayo Clinic, Rochester, Minn., said in an interview.

The double-blind German trial randomized 80 breast cancer patients (median age 53) from April 2002 to October 2004, and was able to evaluate 69. All had at least two hot flashes per day at baseline. None used medication to treat hyper tension or depression. During the 5-week study, 34 patients took 10 mg clomiphene pills per day, 35 patients took venlafaxine in 37.5 mg pills, also twice a day, and 20 patients received a single 400-mg dose, reported Charles L. Loibl, M.D.

The concern is whether MPA interferes with hormonal therapies such as tamoxifen and aromatase inhibitors, Dr. Loibl said.

“There is not a definitive answer,” he said. “You find circumstantial evidence on both sides of the fence.”

His recommended discussing risks and benefits with patients. Dr. Loibl said he believes that risk is minimal because MPA has a half-life of 50 days.

It is a short-term thing,” he said. “I think it is a very small risk.”