Injected Carbon Beads May Curb Fecal Incontinence

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FORT LAUDERDALE, FLA. — Injecting the anal sphincter with microscopic carbon beads led to a promising degree of improvement in fecal incontinence, based on interim results from a phase II study.

Several injection therapies have been tested for fecal incontinence caused by abnormalities of the internal anal sphincter. Injection with Durasphere FI beads is one of the treatments that is most advanced in clinical development. It appears that this approach may relieve symptoms for some patients, but so far no injectables have been approved for this use in the United States, Dr. Eric G. Weiss said at an international colorectal disease symposium sponsored by the Cleveland Clinic Florida.

A multicenter, phase II study enrolled 77 patients who received intersphincteric injections with microscopic, pyrolytic carbon beads in a suspension gel; each bead is 212-500 mcm in diameter. The introduced material is designed to passively close the anal canal and distal rectum and also improve anal symmetry.

The study also enrolled about 40 patients who received injections of saline only; data have not yet been released on these control patients. The study was sponsored by Carbon Medical Technologies, which makes the Durasphere beads.

At baseline, the average Cleveland Clinic Incontinence Score (CCIS) of the 77 patients randomized to receive bead treatment was 12.7, and they had a mean of 21 incontinence episodes every 2 weeks. Their average age was 65 years (range 26-90 years), and 79% were women.

By 1 month after treatment, the average CCIS had dropped to 10.5, with follow-up on all 77 patients. Six-month follow-up data were available for 49 patients, and in this subgroup the average CCIS score was 8.3 (the average CCIS at baseline for this subgroup was 12.4).

This degree of improvement is an important finding because a CCIS of less than 8.5 indicates "significant improvement in quality of life," said Dr. Weiss, a colorectal surgeon at Cleveland Clinic Florida, Weston.

Data from 12-month follow-up were available for 28 patients. In this subgroup, the mean CCIS was 8.2 after 1 year, down from an average of 12.3 at baseline.

Self-assessments by the 49 patients followed for 6 months showed that 41% said their status was much better, compared with baseline, and 29% rated themselves as a little better. Another 22% rated themselves as about the same, 2% said they were a little worse, and 6% self-rated as much worse.

Of the 77 actively treated patients, 24 had a mild adverse event, and 7 patients had a moderate adverse event. No patients had a severe adverse event. The most common adverse events were rectal pain or irritation in 10 patients, an abscess in 10 patients, and bead leakage in 7 patients. Two patients had rectal bleeding, and one patient each had an allergic reaction and anal stiffness.

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Patients were injected with the carbon beads during an outpatient, ambulatory procedure using local anesthesia. In the initial, phase I study, some patients received the beads in the anal submucosal space, but during the study this approach was replaced by injections into the intersphincteric space using ultrasound guidance, which appeared to have better efficacy. The beads were injected at six locations set 60 degrees apart.

Durasphere beads were approved by the Food and Drug Administration in 1999 for treatment of women with urinary incontinence. The beads are approved for the fecal incontinence indication in Europe. The manufacturer is also developing the beads for treatment of gastroesophageal reflux.

Several other injectable materials have been clinically tested for treating fecal incontinence in phase I studies. Results have been reported from studies that used polytef; autologous fat; Contigen, a collagen implant; Bioplastique, a silicone polymer; Solesta, a hyaluronic acid gel; and microballoons. Bioplastique was also tested in a phase II study with 82 patients, Dr. Weiss said. ■

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