

## **AACE: New Hydrogel Diminishes Hunger**

By Kristina Fiore, Staff Writer, MedPage Today Published: April 22, 2010 Reviewed by Zalman S. Agus, MD; Emeritus Professor University of Pennsylvania School of Medicine and Dorothy Caputo, MA, RN, BC-ADM, CDE, Nurse Planner

BOSTON -- A new superabsorbent hydrogel, taken in capsule form, induced satiety and was well-tolerated in normal-weight, overweight, and obese patients, researchers reported here.

Patients taking the new compound, called Attiva, felt significantly fuller after meals compared with those taking placebo, according to Hassan Heshmati, MD, chief medical officer of Boston-based Gelesis, creator of the product.

Heshmati and colleagues presented their findings from a single-center, double-blind, cross-over study at the American Association of Clinical Endocrinologists meeting.

"For years, one of the most important goals in weight management has been the development of an effective treatment that lacks the invasiveness and side effects that surround current approaches," Heshmati said. "This marks an exciting step towards that goal."

Attiva is a highly absorbent, biodegradable polymer hydrogel made from "food components," although the researchers would not elaborate further. The small, spherical particles swell after being ingested with a glass of water.

"It swells hundreds of times when exposed to water," Heshmati said.

The mix of hydrogel and water takes on a polenta-like consistency and fills the stomach, making less room for food.

"This reduction in stomach volume is the mechanism that causes people to eat less," Heshmati said.

The material then passes to the smaller intestine, decreasing its volume and slowing the rate of sugar absorption, making for better glycemic control, Heshmati said.

Finally, it degrades in the colon where it releases the absorbed liquids, and is excreted in feces.

To assess the hydrogel's safety and efficacy, the researchers conducted at Gemelli Hospital in Rome, giving the compound to 95 normal, overweight, and obese patients who had an average body mass index (BMI) of 31.

Overall, 21 patients had a normal BMI, 22 were overweight, and 52 were obese.

Among them, 73 were female, 22 were male, and their mean age was 41.

Each was given two grams of Attiva -- a total of five capsules -- before breakfast, lunch, and dinner with a full glass of water.

No patient received all three doses of Attiva all on the same day; there was a three-day interval between each administration to a single patient.

Satiety was assessed via questionnaire at 30 and 60 minutes after meals on a 0- to 4-point scale, with 0 indicating no satiety and 4 indicating complete fullness.

The researchers found that patients taking the capsules had significantly increased feelings of satiety 30 minutes after breakfast and dinner, and 60 minutes after lunch and dinner, compared with placebo.

Scores 30 minutes after breakfast for the Attiva and placebo groups were 1.85 versus 1.63 (*P*=0.037), respectively; 30 minutes after dinner scores were 1.98 versus 1.70 (*P*=0.004), respectively.

Scores an hour after lunch were 2.35 for the Attiva group versus 2.07 for the placebo group (P=0.007), and 60 minutes after dinner the scores were 2.46 versus 2.15 (P=0.006), respectively.

Heshmati added that those who took Attiva before lunch reported feeling less hungry before dinner -- a socalled "second meal" effect, he said.

The compound was also safe and well-tolerated, with gastrointestinal symptoms, particularly nausea, being the most common side effect occurring in 7.4% of patients taking the capsules.

Heshmati said the capsules are a much more practical means of treating obesity because they are noninvasive, particularly when compared with the highly invasive bariatric surgery.

Attiva was developed by Gelesis, an obesity- and diabetes-focused medical technology group based in Boston. Heshmati is its chief medical officer.

He said the compound would likely be regulated as a device, not a drug or a supplement, because it is considered to have only mechanical action and is essentially a food product. It does not act pharmacologically, he said.

The next step is to see if Attiva affects weight gain. Future trials would investigate chronic administration and focus on obese patients, Heshmati said, "to see if they lose weight."

Heshmati is chief medical officer of Gelesis, Inc., maker of Attiva capsules.

**Primary source:** American Association of Clinical Endocrinologists Source reference: Heshmati HM, et al "Attiva, a novel superabsorbent biodegradable hydrogel, increases the feeling of satiety in humans" *AACE* 2010; Abstract 605.

## **Action Points**

- Explain that patients taking a new superabsorbent hydrogel capsule with water before mealtimes felt significantly fuller after meals compared with those taking placebo.
- Note that this study was published as an abstract and presented at a conference. These data and conclusions should be considered to be preliminary until published in a peer-reviewed journal.

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