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Dual device-drug therapy improves uncontrolled diabetes and obesity

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Combining a temporary one-year intestinal bypass device with the drug liraglutide helps patients lose weight and improve their diabetes control better than using either the device or the drug alone, new research from the United Kingdom reports. The one-year results of the two-year study will be presented in a poster Saturday, April 2, at ENDO 2016, the annual meeting of the Endocrine Society in Boston.

"This is the first study in which the combination of a GLP-1 receptor agonist drug and the endobarrier intestinal device has been used to successfully treat diabetes and obesity. The combination seems to result in the best improvements in both," said Piya Sen Gupta, MBBS, BMedSci, MRCP, research fellow at King's College Hospital London and City Hospital Birmingham, United Kingdom. "The endobarrier is less invasive than surgery, achieves a similar level of bypass, and can be inserted as a simple quick outpatient endoscopic procedure that patients are likely to find more acceptable. They have one year in which to change their eating behavior, and the endobarrier helps to do this."

The endobarrier is a 60 cm (23.6 inch) open-ended, thin, flexible plastic sleeve that is inserted non-surgically through the mouth and lines the upper small intestine to prevent food contact with that portion of the digestive tract. The liner can be removed as desired.

Sen Gupta and her colleagues recruited 70 patients who had difficulty controlling their Type 2 diabetes and were obese despite previous liraglutide treatment. At baseline, all groups were in their early- to mid-

fifties on average with average body mass index around 41 kg/m2.

The researchers randomized participants to one of three groups: 24 patients received an endobarrier and liraglutide; 24 received only an endobarrier; and 22 received only liraglutide.

For the first two weeks, all patients were on the same diet and were given the same dietary information. All participants receiving an endobarrier were implanted with the device for up to one year and assessed every three months. Among the 70 patients, the one-year results show that the endobarrier-plus-liraglutide group and the endobarrier-alone group have lost more weight than the liraglutide-only group (12.8 kg, 12.5 kg and by 4.0 kg, respectively).

Patients receiving both treatments had the best and quickest diabetes improvement (drop in glycated hemoglobin [Hb1Ac] by 2.1%, 1.5% and 1.2%, respectively) achieved despite reduction in other diabetes drugs. The endobarrier was found to be safe, and the combination endobarrier-liraglutide therapy was well tolerated.

All serious device-related adverse events in the endobarrier-treated patients, including gastrointestinal bleed, obstruction, complicated removal and liver abscess were resolved after device removal.

"This is an exciting area of research," Sen Gupta said. "Surgical options such as gastric bypass of a large area of stomach and upper intestine are often successful in improving diabetes and producing weight loss, but they are fairly radical and irreversible options, and are not widely available. Less invasive options that produce similar effects would be ideal, particularly if they result in sustained eating behavior modification."

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