

ADVANCES IN ENDOSCOPY

Current Developments in Diagnostic and Therapeutic Endoscopy

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Endoscopic Management of Obesity

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G&H What is the current role of endoscopy in the management of obesity?

MQ Endoscopic management of obesity can be grouped under the following 3 categories: primary management of obesity; management of obesity-related disorders such as diabetes mellitus and infertility; and management of post-surgical complications. Primary endoscopic management of obesity still falls within the realms of clinical trials and institutional review board–sponsored registries. Most of these studies have been performed in Europe and South America. Due to rising interest in this area, there has been a significant increase in publications over the past few years. Endoscopic management of obesity-related infertility and diabetes mellitus has been described in several case series. There have also been several reports of endoscopic management of extremely obese individuals (body mass index [BMI] >60 kg/m²) prior to performing definitive surgical procedures in order to reduce associated risks. At present, endoscopic treatment is preferred over surgery for postsurgical complications, such as bleeding, dilation of strictured anastomosis, constriction of a dilated anastomosis, and occasionally fistula formation.

G&H What endoscopic techniques are currently being used to promote weight loss?

MQ The endoscopic options currently in use for weight loss could be broadly grouped under the following categories: restriction procedures, malabsorption procedures, and neuromodulation. The largest experience to date is associated with restriction procedures, which include intragastric balloons (BioEnterics Intragastric Balloon

[BIB] and Heliosphere BAG), endoluminal restriction gastroplasty by intermittent sutures (TRIM device) or continuous sutures, transluminal oral gastroplasty (TOGa), and implantable gastric sleeves. Malabsorption procedures include duodenojejunal sleeves. The concept of gastric neuromodulation is still in its infancy, but it is making rapid strides.

G&H Are there any published data on the outcomes of these procedures?

MQ By far, the best-studied device is the intragastric balloon, which was conceptualized several decades ago. Interest in its routine use has been waxing and waning due to some conflicting results over the years. With obesity growing to epidemic proportions, interest in the intragastric balloon has increased significantly. The basic concept of this device is to endoscopically insert an inert balloon in the stomach, inflate it with either saline or air, keep it within the stomach for approximately 6–12 months, and remove it endoscopically. The inflated balloon will mechanically restrict the stomach's capacity to accommodate large volumes of food, resulting in decreased caloric intake and weight loss.

The most-studied intragastric balloon is BIB, which consists of a silastic balloon that can be filled with 500–700 cc of normal saline. In a study from Switzerland, investigators treated 100 patients who had a mean BMI of 35 kg/m² for 6 months and who were followed for approximately 4 years. The investigators found that the mean weight loss at 6 months was 12.6 kg, and 63% of patients had lost more than 10% of their baseline body weight. Mean BMI increased by a mean of 4.2 kg/m² and 2.3 kg/m² in the first and second years of follow-up, respectively. A total of 28 patients maintained their weight loss of more than 10% at the final follow-up (approximately 4 years). In another study, 1 year after balloon insertion, the mean weight loss was 17%, and 47% of patients were

able to sustain weight loss of more than 10% 2 years after removing the balloon.

Endoluminal suturing has been evaluated in several studies. In a study from Venezuela, investigators performed endoluminal vertical gastropasty by continuous sutures and reported excellent results with this minimally invasive procedure. This procedure was performed on 64 patients who were divided into 3 groups: patients with a BMI of more than 40 kg/m², patients with a BMI of 35–40 kg/m², and patients with a BMI of less than 35 kg/m². All of these procedures were performed as outpatient procedures and took a mean of 45 minutes. The mean excess weight loss percentages were 49%, 56%, and 85% at 12 months after the procedure for each of the 3 BMI groups, respectively. There were no significant side effects from these procedures.

Another study was performed in Cleveland, Ohio and Boston, Massachusetts to evaluate any immediate side effects of intragastric cinching. Eighteen patients were enrolled in this study. Approximately 4–7 intragastric anteroposterior sutures were applied. There were no major complications within 24 hours of the procedure, although patients did complain of nausea, vomiting, and abdominal discomfort.

In another study from Boston that evaluated endoscopically implanted duodenojejunal bypass sleeves, investigators examined 39 patients: 25 patients who had the sleeve and were on a low-fat diet and 14 patients who were only on a low-fat diet. At the end of the 12-week study period, mean excess weight loss was 22% and 5%, respectively. The device was explanted in 20% of patients due to bleeding, migration, or obstruction. Long-term results are pending.

TOGA procedures showed promising results in early trials, but subsequent studies have not shown similar results; thus, the device has been shelved at present.

G&H Are repeat procedures necessary in these patients?

MQ In a study from Spain, investigators placed BIB in 714 patients for 6 months and then replaced it in 114 patients after 1 month later (ie, at 7 months). Mean excess weight loss was 44.5%, and the mean BMI decreased from 37.6 kg/m² to 32.9 kg/m² at 6 months and then to 30.3 kg/m² at 1 year. This study suggests that repeat procedures appear to hold some benefit in continuing weight loss, although more research is needed on this issue.

G&H Are there any contraindications to these procedures?

MQ Many investigators have considered the following conditions to be contraindications to balloon placement:

a hiatal hernia more than 5 cm in size, active peptic ulcer disease, severe esophagitis, Crohn's disease, hemorrhagic risk, cancer, esophageal diverticulae and stenosis, severe medical problems, previous gastric surgery, psychological issues, and lack of motivation.

G&H What complications are associated with these procedures?

MQ The complications noted with intragastric balloons—the most-studied of these devices—include nausea, vomiting, balloon migration, abdominal pain, ulceration, perforation, Mallory-Weiss tears, balloon deflation, and weight gain.

G&H Are any of these procedures reimbursable?

MQ The procedures for managing postsurgical complications are reimbursed at the present time. However, reimbursements for the primary procedures are still an issue. As with any new procedures and devices, Current Procedural Terminology codes are issued only after extensive data are available from preclinical and clinical studies. Thus, I suspect that reimbursement will take some time once the procedures are standardized.

G&H Do these endoscopic weight reduction procedures have any other uses?

MQ Intragastric balloons have been extensively studied to evaluate their effect on metabolic syndrome and related disorders. Studies have shown that these devices reduce weight, waist circumference, and fat mass; improve liver steatosis; and restore some components of metabolic syndrome. These devices have also been shown to improve control of diabetes mellitus. In an Italian study, investigators placed intragastric balloons in obese infertile women to evaluate whether weight reduction leads to fertility. Fifteen of the 27 women who underwent balloon placement became pregnant and had live births. In another study, investigators placed intragastric balloons in extremely obese individuals (BMI >60 kg/m²) and found that there was a modest weight loss, which facilitated definitive surgical procedures and decreased complications of surgery.

G&H What are the advantages and disadvantages of using endoscopic techniques for managing obesity as opposed to surgical techniques?

MQ The main advantages of endoscopic methods are that they are reversible, repeatable, less invasive, and associated with increased patient satisfaction. Endoscopic procedures may find a niche for themselves in the man-

agement of obesity-related conditions such as diabetes and infertility, as well as in pretreatment of extremely obese individuals. However, endoscopic procedures for managing obesity are still not fully evolved and, therefore, the comparison to surgery is probably premature. In general, surgery is more invasive and durable, but it is still too early to directly compare them.

G&H Have any studies looked at endoscopic techniques versus existing surgical techniques for management of obesity?

MQ A recent study from Turkey compared laparoscopic gastric bypass with 2 consecutive intragastric balloon placements. A total of 32 patients were studied. Sixteen patients underwent laparoscopic gastric bypass, and the other 16 patients underwent balloon placement for 6 months followed by placement of a second balloon for another 6 months. Excess weight loss between the 2 groups at 6 months was not significantly different, but at 12 and 18 months, patients in the balloon group had significantly higher weight loss compared to the laparoscopic gastric bypass group. According to this study, endoscopic management of obesity is at least comparable to surgical management. However, it remains to be seen if these results can be replicated in other studies. Undoubtedly, there will be a significant increase in interest in endoscopic procedures if these results are consistently replicated.

G&H What training and experience will endoscopists need to perform these procedures?

MQ As these are completely new procedures, gastroenterologists will need training to perform them. Currently, the most important issue is to develop an effective and

standardized procedure, as most of these endoscopic procedures are either experimental or in early stages of development. Hopefully, within the next 5–10 years, we will see these procedures being routinely performed. However, they will not be performed by all gastroenterologists; endoscopic obesity management will likely form a new subspecialty in gastroenterology, as inflammatory bowel disease, hepatology, and endoscopy have done.

Unfortunately, reimbursements may be a hurdle to the development of this field, although it is possible that market forces and the advantages of the procedures—less invasiveness, increased cosmesis, and less pain—will drive development further.

There are currently many exciting devices and procedures being developed. Once proof-of-concept studies are performed, phase II and III human trials will be conducted; although some of these concepts will not be successful, we only need 1 or 2 concepts to be durable and successful for this field to take off.

Suggested Reading

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