Colonoscopy is an effective method of colorectal cancer (CRC) screening that has been shown to reduce CRC risk and mortality by half. People who undergo high-quality exams experience a further 50 percent reduction in risk compared with those whose exam is lower quality.

The main measure of quality is adenoma detection rate (ADR), defined as the proportion of patients in whom at least one precancerous adenomatous polyp is found. In studies, each 1 percent increase in ADR is associated with a 3 percent decrease in development of colorectal cancer and a 5 percent decrease in colorectal cancer death. The current national benchmark for quality is 30 percent for average-risk men and 20 percent for average-risk women, although a 2013 Mayo Clinic study published in *Gastrointestinal Endoscopy* found a higher ADR for both sexes — 25 percent for women and 41 percent for men. An ADR of at least 30 to 35 percent is currently considered high quality.

Michael B. Wallace, M.D., a gastroenterologist at Mayo Clinic’s campus in Jacksonville, Florida, says poor-quality colonoscopies, as measured by a lower ADR, are a problem that can be successfully addressed.

“Our work has focused on increasing the quality of colonoscopy, and in a series of experiments at Mayo Clinic’s Florida campus and now nationally, we have shown that a simple educational intervention involving training and regular feedback to endoscopists can significantly increase ADR,” he explains.

In the original Endoscopic Quality Improvement Program (EQUIP-I) trial, 15 endoscopists at Mayo Clinic’s campus in Florida were randomized to undergo EQUIP training or to serve as controls. The training consisted of two one- to two-hour sessions that reviewed techniques to increase ADR, especially flat adenoma detection, pattern recognition and active bowel cleaning. After completion of the training, ADR was monitored for three months, and intervention endoscopists received private monthly feedback on their performance.

“This was a very active monitoring process; the endoscopists were told they were being monitored and whether they were improving or not. More important, we created a culture of quality, and everyone was very focused on that,” Dr. Wallace says.

Overall, the training program led to significantly improved adenoma and polyp detection rates. At baseline, the ADR for all endoscopists was 36 percent — well above the national average. In the post-training phase, ADR for the EQUIP-trained group increased to 47 percent but remained virtually unchanged for untrained endoscopists. Results of the trial appeared in *The American Journal of Gastroenterology* in 2013.

EQUIP-2, a five-month follow-up study, examined an additional 1,200 colonoscopies and found that the improved ADR in the trained group was maintained at 46 percent whereas ADR in the untrained group increased only slightly to 39 percent. The study appeared in 2015 in *The American Journal of Gastroenterology*.

Based on these results, Mayo researchers hypothesized that EQUIP training would increase ADR in a multicenter clinical practice setting and that the gains would be durable. To test this theory, they randomly assigned endoscopists at five large clinical centers to receive in-person training with active feedback and endoscopists at four control sites to receive training and feedback at the end of the study only.

Nearly 23,000 colonoscopies were performed during the study period. ADRs and other quality
measures were evaluated at baseline and during a post-training period using the GI Quality Improvement Consortium (GIQuIC) monitoring system.

Study results, which were presented at ACG 2015 and later published in The American Journal of Gastroenterology, showed a statistically significant increase in ADR from 31 to 42 percent among trained endoscopists compared with an increase of just 36 to 39 percent among controls. In a multivariate model, however, the difference between groups was not significant (OR = 1.03; 95 percent CI, 0.84-1.25).

“We observed that ADR increased significantly after training,” Dr. Wallace says. “There was a small but insignificant increase in the control group, but there was no significant difference between the intervention group and control group. We saw the greatest gains in screening examinations in physicians who had low baseline ADR. We suspect the Hawthorne effect — the effect of just knowing you are watched — led to improvement in the control group.”

Current and future trends
Mayo Clinic’s campus in Florida maintains an active feedback program — every physician receives a quarterly ADR report card. The nine participating centers in EQUIP-3 also will continue to receive active feedback as part of a national program run by GIQuIC, a national registry with a database of 2 million colonoscopies.

“There is strong international recognition that we need to monitor adenoma detection rates, and groups around the country are actively participating in these registries, particularly GIQuIC,” Dr. Wallace explains. “Other countries that provide national colonoscopy screening, especially the U.K., Australia and Germany, have similar quality monitoring programs — some more active than in the U.S. Our work is part of a large number of parallel trials.”

EQUIP has had a broad impact: Dr. Wallace devised and implemented a webinar-based intervention for Veterans Affairs hospitals throughout the U.S. and for the New York State Department of Health.

“There is a broad consensus that ADR is a good way of measuring quality,” he says. “It’s a surrogate marker that is very tightly linked with the prevention of colon cancer, and we know that patients of doctors with higher adenoma detection have a lower cancer risk within the next five to 10 years. There is an emphasis on expensive technology, but focusing on inexpensive interventions like technique and education has a greater impact.”

For more information


Most Patients With HCV Cured With New Drugs — But at What Price?

The revolution in treatment for hepatitis C virus (HCV) infection continues at an unprecedented pace, especially for genotype 1, which affects approximately 75 percent of patients with HCV in the United States. By the end of 2015, four Food and Drug Administration-approved, all-oral regimens of direct-acting antiviral agents were available, most with a sustained virologic response (SVR) above 95 percent, even in patients who failed prior interferon-based triple therapy. SVR is equivalent to a cure because the durability of response is nearly universal; unfortunately, however, response to treatment does not protect patients from reinfection.

The new antiviral agents include Harvoni — sofosbuvir combined with the NS5A inhibitor ledipasvir; Viekira Pak, a combination of ombitasvir, paritaprevir and ritonavir plus dasabuvir; and Olysio (simeprevir) combined with Sovaldi (sofosbuvir). These regimens are effective against genotypes 1a and 1b.
The NS5A inhibitor Daklinza (daclatasvir) is approved for use with sofosbuvir for chronic genotype 3 HCV infection. A fourth drug regimen, Technivie — combined ombitasvir, paritaprevir and ritonavir — is approved for treatment of genotype 4 HCV without cirrhosis in combination with ribavirin.

Of the interferon-free treatment options for genotype 1 HVC, the fixed-dose combination drug Harvoni provides the simplest regimen and has demonstrated efficacy in patients with advanced liver disease, including decompensated cirrhosis. Harvoni is taken as a single pill, once daily for 12 weeks or for 24 weeks in patients with cirrhosis, with a sustained viral response rate of 95 percent. It has a relatively clean side effect profile and few drug-drug interactions.

It is also expensive, with a price tag close to $1,000 a pill. In the first half of 2015, Medicare’s prescription drug program spent nearly $4.6 billion on new HCV medications, including 119,000 prescriptions for Harvoni.

Viekira Pak, which was approved later than Harvoni and has since been linked to serious liver problems in patients with underlying cirrhosis, requires a more nuanced approach, according to Hugo E. Vargas, M.D., vice chair of Hepatology at Mayo Clinic’s campus in Scottsdale, Arizona.

“Viekira Pak has a greater pill burden than Harvoni, and the spectrum of patients it can treat is more limited — it is contraindicated for those with moderate to severe hepatic impairment. Although it is still effective for a significant portion of patients, that effectiveness is shadowed by those factors. On the plus side, it’s about 12 percent less expensive than Harvoni, and its presence in the market has decreased the cost of treatment for all patients,” he says.

Daclatasvir plus sofosbuvir is an all-oral, once-daily regimen for difficult-to-treat genotype 3. In phase III trials, it achieved SVR12 in 96 percent of patients without cirrhosis who had not been treated before. Patients with genotype 3 who have prior treatment exposure and cirrhosis have lower response rates with interferon-free regimens. Still, of the few options for patients with decompensated cirrhosis, daclatasvir is the only agent recommended across genotypes.

Two new, all-oral regimens will likely be approved in 2016 that may further close the gaps that currently exist in the management of HCV.

**The price of a cure**

Virological efficacy, ease of use and tolerability make interferon-free, direct-acting antiviral regimens the best treatment option for all patients, even those with relatively mild fibrosis, Dr. Vargas says.

“Studies, including a Centers for Disease Control and Prevention study published in *Clinical Infectious Diseases* in 2015, have shown that deferring treatment leads to detrimental outcomes, such as progression to cirrhosis, hepatic decompensation and hepatocellular carcinoma. There is also an immediate benefit to treating people with early disease — quality of life and survival both improve, and patients are much more likely to have a reversal of damage. Treating sooner instead of warehousing patients until they become sicker makes much more sense from both an individual and a public health standpoint,” he explains.

Insurers, however, are often reluctant to cover people who don’t have advanced cirrhosis or fibrosis even though such an approach only addresses the final and most dramatic manifestations of HCV infection. Thus, assessment of the extent of liver disease is more critical than ever in patients with HCV, says Andrew P. Keaveny, M.D., chair of Transplant Medicine at Mayo Clinic’s campus in Jacksonville, Florida.

“We are able to offer state-of-the-art noninvasive testing for liver fibrosis at all three Mayo sites, including point-of-care transient elastography as well as magnetic resonance elastography, which was developed at Mayo Clinic,” he explains.

But debate still rages as to how much high-priced HCV medications will save the broader health system by preventing liver transplants and other costs associated with hepatic disease.

“It’s an extremely difficult decision to tell patients they have to wait on therapy because the price is too high,” Dr. Vargas observes. “All the interested parties have to come together and voice their concerns in order to arrive at a commonsense solution. Doctors, patients, pharmaceutical interests and the third-party payers have to engage in a dialogue to arrive at a national strategy that will lead to broad coverage of these effective new agents. The entry of more new HCV agents into the marketplace over the next 12 months will likely exert price pressure, too.”

For now, Dr. Vargas says the daunting prices shouldn’t keep patients with HCV from seeking care.

“All patients deserve to be considered. At all three Mayo sites, we can easily and noninvasively assess each patient’s needs, make recommendations and serve as advocates,” he says.

**For more information**

Creative Alternatives Needed for IBD Comparative Effectiveness Research

Efficacy-based randomized clinical trials are designed to determine how well a particular — and usually unproven — intervention might work under ideal circumstances compared with placebo. These trials, which use data-driven numeric outcomes and exclude critical patient groups, bear little resemblance to real-world practice, yet their findings may influence clinical decision-making.

Effectiveness trials, on the other hand, assess how well a particular intervention works compared with other options commonly used in clinical practice. Ideally, comparative effectiveness research (CER) also identifies the features that predict which intervention would be most effective in any one patient. This type of research is intended to foster evidence-based changes in practice that reduce costs and improve patient care.

The 2009 American Recovery and Reinvestment Act designated $400 million in discretionary funds to accelerate CER efforts, and among other areas of study, the Institute of Medicine prioritized research comparing different strategies of introducing biologics in the treatment algorithm for inflammatory bowel disease (IBD).

Arguably the most well-known IBD effectiveness study is the landmark SONIC trial, which compared early use of infliximab plus azathioprine to monotherapy with either drug in patients naive to corticosteroids, immunomodulators and anti-tumor necrosis factor (anti-TNF) agents. The findings, published in the New England Journal of Medicine in 2010, showed that patients receiving combination therapy had higher corticosteroid-free remission rates at 26 weeks — the primary endpoint — than did patients receiving infliximab or azathioprine alone. Infliximab alone was also shown to be more effective than azathioprine monotherapy.

Although the SONIC trial led to increased use of combination therapy in Crohn’s disease (CD), the small sample size of this and other CER trials is a significant limitation. Effectiveness trials require substantially larger patient populations than placebo-controlled trials, which makes them far more costly and harder to recruit.

“It’s becoming increasingly difficult to recruit and enroll patients, which has led to the globalization of clinical trials — sponsors are now going far afield, to eastern Europe, India and Russia in order to conduct trials more easily and cost effectively,” explains Edward V. Loftus Jr., M.D., a gastroenterologist at Mayo Clinic’s campus in Rochester, Minnesota.

Is there a better way?

One alternative that avoids some of the challenges of head-to-head prospective trials is network meta-analysis, which allows investigators to make inferences about the effectiveness of interventions that have not been directly compared with one another. For example, in a 2014 study published in Alimentary Pharmacology and Therapeutics, Mayo Clinic researchers performed a network meta-analysis of all approved biological agents for treatment of ulcerative colitis in first-time biologic users.

On indirect comparison of nine trials, no single agent proved clearly superior to others. Although patients taking infliximab were twice as likely to achieve remission as those on adalimumab, the difference was not statistically significant.

A similar Bayesian network meta-analysis of 17 randomized controlled trials comparing six biological agents for Crohn’s disease suggested that infliximab was the most effective for inducing clinical remission in first-time biologic patients. All other agents seemed to work equally well in patients who responded to the index biologic agent, although adalimumab, natalizumab and infliximab were favored.

The investigators note that their findings, which were published in Mayo Clinic Proceedings in 2014, have lower confidence because they are based solely on indirect treatment comparisons and do not take into account cost, safety and patient preference — all of which must be factored into treatment decisions.

In another approach, Mayo Clinic investigators took advantage of the unique partnership between Mayo’s Center for the Science of Health Care Delivery and Optum Labs to compare the effectiveness of anti-TNF agents approved for treatment of CD using a large health care claims database. In a cohort of biologic-naïve patients, they found that infliximab was superior to both adalimumab and certolizumab for clinically relevant outcomes, including reduced new steroid prescriptions and CD-related hospitalizations and surgeries. Study findings were presented at Digestive Disease Week 2015.

Dr. Loftus notes that although head-to-head prospective trials remain the holy grail, they present ongoing challenges. “We need to do more CER, but who is going to pay? Pharmaceutical companies would prefer placebo-controlled trials because it is easier to demonstrate the efficacy of their therapeutic agents,” he says. “Having said that, in the pipeline are several companies willing to perform comparative trials of anti-integrin
Irritable bowel syndrome (IBS) is a multifactorial disorder marked by recurrent abdominal pain or discomfort and altered bowel function with no detectable organic cause on standard testing. It has long been considered a diagnosis of exclusion, and management is based primarily on symptoms. IBS affects about 20 percent of people in the developed world; approximately one-third have IBS with diarrhea (IBS-D).

Alterations in various gastrointestinal (GI) functions provide potential biomarkers for diagnosing and treating IBS-D. But most biomarkers proposed to date appear to lack sufficient sensitivity and specificity to distinguish IBS-D from gastrointestinal diseases with similar symptoms or to lead to treatments that relieve symptoms or restore normal function. This includes markers cited in studies from 2015, such as densities of rectal peptide YY-containing cells, elevated serum anti-cytolytic distending toxin B and anti-vinculin titers, and dysbiosis index.

**Identifying actionable biomarkers**

Michael Camilleri, M.D., director of the Clinical Enteric Neuroscience Translational and Epidemiological Research (C.E.N.T.E.R.) Program at Mayo Clinic’s campus in Rochester, Minnesota, argues, however, that promising, actionable IBS biomarkers already exist.

“The current literature suggests that proposed biomarkers aren’t ready for prime time — that is, they are insufficiently sensitive and specific to differentiate healthy individuals from those with disease or IBS-D from other diarrheal illnesses. But there are very specific ways to differentiate conditions such as inflammatory bowel disease or celiac disease,” he says. “Furthermore, in addition to being indicators of normal biological or pathogenic processes, actionable biomarkers are also used to predict pharmacological responses to therapeutic interventions.”

Thus, the focus should not be restricted to the discovery of diagnostic IBS biomarkers, he says, but also should include those that are prevalent — occurring in at least 25 percent of IBS patients — and represent targets for treatment with available medications. In a 2015 paper published in *Alimentary Pharmacology & Therapeutics*, Dr. Camilleri cites four classes of actionable targets: serotonin, inflammation, colonic transit, and bile acid malabsorption. The latter two have the greatest potential for identifying subgroups responding to available and approved IBS therapies.

**Colonic transit**

The largest study of colonic transit in IBS to date, which looked at 287 patients with functional lower GI disorders, appeared in *Neurogastroenterology & Motility* in 2010. The study found that at 24 hours, colonic transit was delayed in 24.5 percent of patients with IBS-C and accelerated in 33 percent of those with IBS-D. In addition, colonic transit was delayed in 23 percent of IBS-C patients at 48 hours, suggesting that colonic transit is abnormal in about one-third of patients with IBS-C or IBS-D.

Colonic transit is significantly associated with clinical symptoms such as stool consistency and frequency, and has correctly predicted the efficacy in clinical trials of 18 medications used or in development for lower GI disorders, all of which were later approved and marketed (Table).

**Bile acid malabsorption**

It is estimated that bile acid malabsorption (BAM) occurs in one-third of patients diagnosed with IBS-D and up to 50 percent of those with

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For more information


functional diarrhea. The gold standard test for BAM is 75 selenium homocholic acid taurine (SeHCAT) retention, measured by external scintigraphy, usually seven days after oral administration of a gamma-emitting synthetic bile acid. Diagnostic accuracy is high, with 100 percent sensitivity and 94 percent specificity. Unfortunately, the test isn’t widely available in many countries, including the United States.

A systematic review published in *Alimentary Pharmacology & Therapeutics* in 2009 evaluated the prevalence of BAM in 1,223 patients with IBS-D.

<table>
<thead>
<tr>
<th>Drug class</th>
<th>Pharmacodynamics (intestine or colon)</th>
<th>Clinical efficacy: Phase IIB or III studies</th>
</tr>
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<tbody>
<tr>
<td>5-HT3-agonist, alosetron</td>
<td>Delayed colon transit diarrhea in IBS-D at 1 mg twice a day</td>
<td>IIB, III studies in thousands of patients with non-IBS-C or non-IBS-D showed adequate relief of pain and discomfort of IBS, bowel dysfunction (including diarrhea) and urgency</td>
</tr>
<tr>
<td>5-HT4-agonist, tegaserod</td>
<td>Accelerated SB transit and colon transit in healthy people and people with IBS-C (without evacuation disorder) at 2 mg twice a day</td>
<td>IIB, III studies in several thousands of patients with IBS-C and CC experienced relief of pain and discomfort of IBS and bowel dysfunction</td>
</tr>
<tr>
<td>5-HT4-agonist, prucalopride</td>
<td>Increases SB and colon transit in healthy people</td>
<td>IIB and III in CC studies (thousands of patients); BM frequency and satisfaction with bowel function both improved</td>
</tr>
<tr>
<td>5-HT4-agonist, velusetrag</td>
<td>Dose-related increase in SB and colon transit in healthy people</td>
<td>A IIB, dose-ranging study in 401 CC patients increased BM frequency and proportion with adequate relief</td>
</tr>
<tr>
<td>5-HT4-agonist, YKP10811</td>
<td>Accelerates colon transit and improves stool consistency in CC</td>
<td>ClinicalTrials.gov: NCT01989234; study completed, no posted results</td>
</tr>
<tr>
<td>Bisacodyl</td>
<td>Accelerates colon transit in healthy people</td>
<td>Relief of constipation after acute administration and CC</td>
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<tr>
<td>Recombinant human neurotrophin (NT)-3</td>
<td>Accelerates colon transit in CC</td>
<td>NT-3, administered TTW, increased stool frequency; accelerated colon transit and improved symptoms of chronic constipation</td>
</tr>
<tr>
<td>Cl-C2 channel activator, lubiprostone</td>
<td>Accelerates SB and colon transit in healthy controls</td>
<td>Several phase III studies in several hundred patients with CC and IBS; efficacious in relief of pain and bowel dysfunction</td>
</tr>
<tr>
<td>Guanylate cyclase-C agonist, linaclotide</td>
<td>Accelerated AC transit and induced looser bowel function in 36 women with IBS-C</td>
<td>Several IIA, IIB and III studies in CC or IBS-C (several hundred patients); increased BM frequency, relief of bloating and abdominal discomfort</td>
</tr>
<tr>
<td>GLP-1 analog, ROSE-010</td>
<td>Accelerated colon transit at 48 h</td>
<td>Relieved severity of pain attacks and enhanced satisfaction score in IBS patients</td>
</tr>
<tr>
<td>Ileal bile acid transport inhibitor, elobixibat</td>
<td>Accelerates colon transit and loosens stool consistency in functional patients with constipation</td>
<td>One phase IIB study showed improved stool frequency, and improved constipation-related symptoms in idiopathic CC</td>
</tr>
<tr>
<td>Bile acid sequestrant, colesuvelam</td>
<td>Retards ascending colon emptying</td>
<td>Improves stool consistency in IBS-D with high fecal BA excretion (phase IV study)</td>
</tr>
<tr>
<td>VSL#3 combination probiotic</td>
<td>Retards colon transit in IBS-D, improves flatulence and bloating in IBS-D</td>
<td>Meta-analyses demonstrate symptom relief of multiple symptoms in IBS; global IBS, abdominal pain, bloating and flatulence scores</td>
</tr>
<tr>
<td>κ-opioid agonist, asimadoline</td>
<td>No significant effect on colon transit in healthy volunteers</td>
<td>On-demand dosing not effective in reducing severity of abdominal pain in 100 IBS patients; a phase IIB study, dose-ranging in 596 IBS patients, post hoc analysis: benefit in moderate pain in IBS-D and Alt-IBS</td>
</tr>
<tr>
<td>CCK1-antagonist, dexloxioglimide</td>
<td>Slower AC emptying with no effect on overall colon transit in IBS-C</td>
<td>Two initial IIB or III trials: not efficacious in IBS-C; a randomized withdrawal design trial showed longer time to loss of therapeutic response for dexloxioglimide</td>
</tr>
<tr>
<td>CRH2-antagonist, pexacerfont</td>
<td>No effect on colon transit and bowel function in IBS-D</td>
<td>One phase IIB study showed GW876008 had no significant difference from placebo in the global improvement scale, daily self-assessment of IBS pain/discomfort or individual lower GI symptoms</td>
</tr>
<tr>
<td>κ-3 adrenergic agonist, solabegron</td>
<td>No significant effect on gastrointestinal or colon transit</td>
<td>One phase IIB study showed no significant change in bowel symptoms, although there is significant effect on adequate relief of IBS pain and discomfort</td>
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**Table.** Evidence of clinical efficacy predicted by colonic transit measured by scintigraphy. Based on *Alimentary Pharmacology & Therapeutics.*
Findings included the following:

- 10 percent of patients had severe bile acid malabsorption as measured by a SeHCAT seven-day retention of less than 5 percent of baseline value.
- 32 percent of patients had moderate bile acid malabsorption — SeHCAT retention less than 10 percent.
- 26 percent of patients had mild bile acid malabsorption — SeHCAT retention less than 15 percent.

Pooled data also showed a concordance correlation between treatment with the bile acid binder cholestyramine and severity of malabsorption; response to the drug occurred in 96 percent of patients with less than 5 percent retention, 80 percent at 10 percent retention and 70 percent at 15 percent retention.

Since the original review of bile acid malabsorption based on SeHCAT, the same Mayo Clinic research group has confirmed that about 30 percent of patients with IBS-D or functional diarrhea have bile acid malabsorption based on four types of tests: SeHCAT, serum 7-alphaC4, serum PGF19 and 48-hour fecal bile acid excretion. Results of their meta-analysis appeared in *Gut* in 2015.

“Using biomarkers that characterize a trait that is a target for treatment has been successful in both scintigraphic measurement of colonic transit and SeHCAT studies,” Dr. Camilleri says. “Identifying subgroups with the greatest responsiveness and individualizing treatment reduces the risks of adverse effects and may ultimately spur drug development and reduce costs for patient care.”

For more information


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**Intragastric Balloon Safe and Effective in Total Weight Management Program**

More than one-third of American adults are obese, with a body mass index (BMI) of 30 kg/m² or greater. Obesity is associated with functional impairments and comorbidities, including hypertension, cardiovascular disease, metabolic disorders, arthrosis and obstructive sleep apnea. In the U.S., it accounts for 18 percent of deaths among people ages 40 to 85.

Despite advances, obesity management remains challenging. Diet and exercise often don’t produce significant and sustained weight loss. And although bariatric surgery produces durable weight loss and shows the most promise for diabetes resolution, only about 2 percent of people who qualify for surgery undergo it.

“There is a big gap in the management of obesity, where diet and exercise aren’t enough but patients either don’t qualify for a surgical option or don’t want it because of the cost and risks. People who fall into this gap represent the majority of those with mild to moderate obesity,” says Barham K. Abu Dayyeh, M.D., a gastroenterologist who specializes in bariatric and metabolic endoscopy at Mayo Clinic’s campus in Rochester, Minnesota. “For these patients — with a BMI of 30 to 40 kg/m² — the newly approved intragastric balloon procedure represents an intermediate option between lifestyle change and bariatric surgery.”

**Intragastric balloons — Then and now**

The use of an endoscopically placed intragastric balloon to treat obesity was first described in the early 1980s. An air-filled polyurethane device, approved by the Food and Drug Administration (FDA) in 1985, was later withdrawn due to a lack of supportive efficacy data and a high rate of serious complications.

The new generation of intragastric balloons are made of silicone, implanted in the stomach endoscopically and filled with a saline solution up to 650 cm³ through a self-sealing valve. The outpatient procedure takes less than 20 minutes, and the device is removed six months later.

In August 2015, the FDA approved two intragastric balloon systems, including Apollo Endosurgery’s Orbera system, which has been used outside the U.S. since 1997. Approval was...
largely based on efficacy and safety data from a two-year multicenter clinical trial, which Dr. Abu Dayyeh presented at Digestive Disease Week 2015 in Washington, D.C. The Orbera trial
In the trial, 125 patients were randomly assigned to balloon treatment and a 12-month behavioral therapy program; 113 patients receiving only behavioral management served as controls. The majority of participants were female, with a mean BMI of 35 kg/m\(^2\) and mean excess weight of 36 kg. Both groups were followed for 52 weeks. Findings from the study include:
• The balloon group lost significantly more weight than did the control group over the course of the study and was able to maintain it at one year — six months after balloon removal.
• At one year, the balloon group lost 29.29 percent of their excess weight compared with 14.2 percent in the control group, surpassing efficacy thresholds set by the American Society for Gastrointestinal Endoscopy (ASGE) and the American Society for Metabolic and Bariatric Surgery. The ASGE recommendations were published in *Gastrointestinal Endoscopy* in 2011 and 2015.
• Both groups experienced a reduction in comorbid conditions, such as diabetes, hypertension and dyslipidemia, but the reduction was greater among balloon patients, who also experienced improved quality of life as measured by Beck Depression Inventory scores.
• Serious adverse events were rare in the intragastric balloon group.

Dr. Abu Dayyeh says the balloon procedure is safe and fully reversible. Severe side effects, such as small bowel obstruction, perforation or tears in the stomach, and bleeding are rare.

“Many patients experience nausea and epigastric pain in the first week after implantation, but these are usually easily managed with medication and typically resolve in a few days after the stomach adjusts to the balloon,” he explains.

Comprehensive obesity program
The intragastric balloon aids weight loss by slowing the rate at which food enters the stomach and by stimulating gastric stretch receptors. But lifestyle changes, including behavior modification, exercise and healthy diet, are crucial for maintaining weight loss once the device is removed.

“The balloon is just one part of a comprehensive, 12-month obesity program we use to support patients in their weight-loss journey,” Dr. Abu Dayyeh explains. “This is a strong, highly multidisciplinary program unique to Mayo that uses innovative, proven tools to help people with a BMI of 30 to 40 who aren’t ready or don’t qualify for surgery.”

For more information