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ALL THE POSSIBILITIES OF MODERN MEDICINE

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Metabolic Surgery:

New Option in Treating Type 2 Diabetes

William B. Inabnet, MD
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As increasing numbers of people have chosen bariatric surgery, doctors have observed, and research has confirmed, that 83% of patients experience a complete remission of type 2 diabetes after gastric bypass surgery (the gold standard in weight loss procedures), even before weight loss occurs. This is enormously significant, given the devastating impact of diabetes on public health in the U.S., and increasingly, throughout the world. Endocrine surgeon-researchers at the Columbia University College of Physicians and Surgeons are working to understand the reasons behind this unexplained benefit.

Among those undergoing laparoscopic banding procedures, type 2 diabetes resolves in about half of patients—also tremendously significant. "What is especially striking is that the resolution of diabetes occurs almost immediately after surgery, and before significant weight loss," according to **William B. Inabnet, MD,** *Chief, Endocrine Surgery Section* and *Co-Director, New York Thyroid/Parathyroid Center.* "Many patients can stop taking their diabetes medications shortly after surgery," he explains.

While resolution of diabetes after weight loss surgery clearly benefits those who are eligible for surgery (people with body mass index greater than 35), a study underway at Columbia University Medical Center is the first in the United States to explore surgically treating type 2 diabetes in people who are not obese, says Dr. Inabnet. "Understanding how weight loss surgery improves diabetes may lead to new ways of improving blood glucose control and ultimately help researchers identify a cure for type 2 diabetes."

DIABETES AND WEIGHT LOSS SURGERY

Researchers believe that bypassing the upper part of the intestinal tract, the 'foregut,' through surgery may cause hormonal changes that lead to improvement in diabetes. "We know that the gut is a major player in diabetes resolution, that there is a pathway of communication between beta cells (insulin producing cells in the pancreas), the hunger center in the brain, and adipose tissue," says Dr. Inabnet.

The gastrointestinal tract is the largest and most active endocrine organ in the body, and produces more than 100 hormones. One theory holds that after gastric bypass surgery, nutrients are delivered more quickly to the 'hindgut,' or the lower portion of the intestinal tract, where certain hormones such as GLP1 are released. GLP1 acts on beta cells, which make insulin. **Judith Korner, MD, PhD,** *Assistant Professor, Department of Medicine* and *Director, Weight Control Center, Columbia University Medical Center,* explains that "Delivery of nutrients to the distal gut may help to stimulate hormones that regulate blood glucose. We are not sure whether the resolution of diabetes is caused by bypassing the foregut, or rapid delivery of nutrients to the distal gut, or both."

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Scarless Surgery

The Future of Surgery: No Scars in Sight

Moving beyond laparoscopic surgery's small incisions, surgeons at the Department of Surgery are committed to improving surgical techniques even further. The wave of the future, according to **Marc Bessler, MD,** *Director, Minimal Access Surgery Center,* holds the promise of surgery that leaves no visible trace at all. Dr. Bessler and colleagues are using, testing, and refining three new methods of performing surgery that leave no external scars on the body.

ENDOLUMENAL SURGERY

Endolumenal surgery is performed by inserting fine instruments through a natural orifice such as the mouth. This approach is currently being used to prevent acid reflux by inserting a tube into the mouth and esophagus and creating a valve at the point where the esophagus meets the stomach (the esophago-gastric junction). Employing a device approved by the FDA in 2007 (EsophyX™), the procedure may provide an important alternative to medication for the 30 million Americans with chronic, progressive reflux disease.

In endolumenal weight loss surgery, surgical instrumentation is advanced through the mouth into the stomach, where it is used to staple or suture the stomach pouch from the inside. The reduced stomach pouch limits food intake in a similar fashion to the gastroplasty or banding procedures, but without any incisions in the abdomen or leaving a device in place. This approach is approved in Europe as a weight loss procedure, and is available in the U.S. for revisional surgery to help patients who have regained weight after an initial weight loss procedure. At this time, the Transoral Gastroplasty (TOGA®) trial is enrolling patients at Columbia to evaluate the use of this investigational approach as a first-line approach to weight loss surgery.

In addition to esophageal and weight loss procedures, endolumenal surgery is being used to remove small tumors or polyps from the stomach.

TRANSLUMENAL SURGERY

Natural orifice endoscopic translumenal surgery, or NOTES, also entails the use of fine instrumentation advanced through a natural orifice such as the mouth, vagina, or rectum. In this approach, once the instrumentation is in place, an incision is made through an internal organ in order to access the abdominal cavity and perform the surgery. This approach may be used for operations such as:

- gallbladder removal through an incision in the vaginal wall;
- appendix operations performed through the vaginal wall;
- intestinal biopsies, or removal of parts of the intestine, performed with instrumentation advanced through the rectum; and
- removal of lesions in the colon, also via the rectum.

Operations through incisions in the stomach may also be performed in the future, but this approach carries risk of leakage if the stomach incision does not heal well. The vaginal approach does not present this risk, explains Dr. Bessler.

Small incisions through the vaginal or intestinal wall leave little or no pain, because those tissues have minimal pain sensation, and patients experience faster recovery than after open or laparoscopic procedures. Initially performing the procedure with one laparoscopic incision, surgeons at Columbia have been able to ensure safety and perform the procedure with no skin incisions.

Jada Fabrizio

TRANSUMBILICAL SURGERY

Transumbilical surgery, also called 'single incision surgery,' involves the use of one small incision in the belly button. With three or four instruments advanced through that single incision, Dr. Bessler and colleagues can do the following:

- remove the gallbladder;
- insert or remove adjustable gastric bands for weight loss;
- perform sleeve gastrectomy for weight loss;
- remove the appendix;
- correct hernias; and
- surgically treat gastroesophageal reflux.

As with the procedures discussed above, this approach provides a minimally invasive alternative with excellent access to the abdominal organs and little or no visible scar.

Evolution from standard laparoscopy to surgery with no external scars depends on refinement of the miniature surgical and imaging tools that surgeons use in this approach, and the training of surgeons in the use of these new methods. At this time, select surgeons in the Department of Surgery are offering scarless procedures as part of clinical studies and limited protocols. TOGA patients have been losing weight, patients are not needing pain medication after EsophyX for reflux, and overall, patients are recovering quickly and very well, reports Dr. Bessler. "Since laparoscopic surgery requires three to five incisions, these scarless approaches will make surgery even easier for patients," he states, "So far most patients have been very pleased with the results." ■

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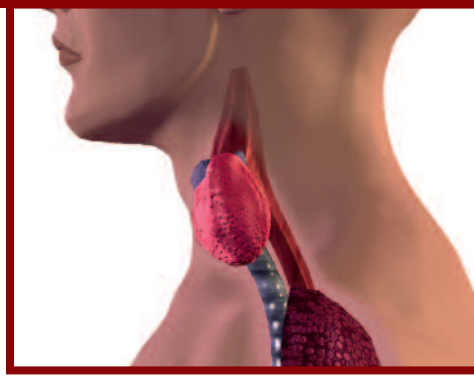
Thyroid Cancer

Thyroid cancer has the fastest rising incidence among all cancers affecting women in the United States.



The thyroid gland

Advances in the treatment of thyroid cancer are improving the quality of life of patients at Columbia University College of Physicians and Surgeons.

Thyroid cancer is the most common endocrine malignancy, and typically affects young and middle-aged women. If the disease is diagnosed early and treated properly, most patients have a very good prognosis, so early diagnosis is key, according to **Robert McConnell, MD,** Co-Director of Columbia's *New York Thyroid/Parathyroid Center*.

LOCAL OR LOCO-REGIONAL ANESTHESIA

Surgery to remove cancerous nodules of the thyroid traditionally has been performed under general anesthesia. Since the late 1990's, patients at Columbia have received treatment under local or loco-regional anesthesia, and can return home the same day (instead of staying at the hospital three to five days). This inpatient procedure was pioneered at Columbia by the late Paul LoGerfo, MD, in order to provide patients with a less traumatic procedure and faster recovery. According to Dr. McConnell, "Patients feel far better after this type of surgery than after general anesthesia." Although this approach has been standard of care at Columbia for many years, only now is it becoming widely adopted across the country.

THYROGEN THERAPY

Following surgery for thyroid cancer, many patients are treated with radioactive iodine in order to eliminate any residual cancer

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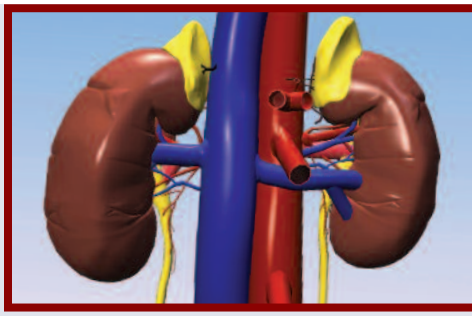
Advances in Adrenal Surgery

Columbia surgeons are testing a new approach to removing benign adrenal tumors.



The adrenal glands are located immediately above the kidneys.

The adrenal glands, located adjacent to the kidneys, produce hormones including aldosterone, cortisol, adrenaline, testosterone, and estrogen. Tumors may form in the glands, causing overproduction of one or more of these hormones. In such cases, surgical removal of the tumor may be necessary.

At the Department of Surgery, endocrine surgeons are utilizing a new approach, retroperitoneal adrenalectomy, to remove such tumors. In this procedure, the surgeon makes three laparoscopic incisions in the patient's back underneath the rib cage. Through these tiny ports, he or she inserts surgical and imaging instruments and removes the tumor.

At virtually every other U.S. center, laparoscopic adrenalectomy is performed through the belly, according to **James A. Lee, MD,** *Director, Columbia Adrenal Center*. When the surgical approach to the tumor comes from the back, patients seem to experience less pain and have fewer complications such as hernias, he explains. In addition, the new procedure takes half as much time as the traditional approach (about 30 to 45 minutes compared to an hour or hour and a half). As an added benefit, patients may prefer the retroperitoneal approach for cosmetic reasons.

Dr. Lee and **William B. Inabnet, MD,** *Chief, Endocrine Surgery Section* and *Co-Director, New York Thyroid/Parathyroid Center,* brought the new approach back to the U.S. after learning it in Germany, where surgeons developed and perfected the technique.

Although there is plenty of evidence to support the benefits of a retroperitoneal approach, Adrenal Center physicians want to make sure that this technique really does offer significant benefits to their patients. In a randomized, controlled trial at Columbia University Medical Center, half of patients will have surgery via the traditional frontal approach, while the other half will undergo the retroperitoneal procedure. Eligible patients cannot be morbidly obese, and their tumors must be less than six centimeters in size.

This new approach represents one of many ways in which the Adrenal Center is working to advance the care of patients with adrenal disease.

Always looking to the next frontier, Dr. Lee says, "We are currently using three incisions to do this procedure, but we expect to be able to do this through a single incision in the near future." ■

Thyroid Cancer ~ continued from page 3

cells. Traditionally, patients have had to avoid taking any thyroid medication for several weeks in order to undergo this treatment (called remnant ablation), and during the withdrawal period, they have had to endure the uncomfortable, sometimes debilitating symptoms of hypothyroidism (fatigue, muscle aches, pains, memory impairment, depression, weight gain, and more).

At Columbia, patients need not go through weeks of feeling poorly. Instead of withdrawal from thyroid hormone prior to radioiodine therapy, they can receive thyrotropin alpha, or Thyrogen®, an injectable thyroid stimulating hormone. Thyrogen was first approved by the FDA in 1998 as a diagnostic tool (because it increases the sensitivity of the thyroid during testing), and then in 2007 for use during remnant ablation. According to Dr. McConnell, "Post-Thyrogen remnant ablation is as effective as withdrawal therapy, but patients feel well."

THYROGLOBULIN IN FOLLOW-UP CARE

After treatment for thyroid cancer, patients must continue to receive regular monitoring for signs of recurrence, which may occur in up to 30% of patients. For patients at low risk, the standard method is to measure levels of thyroglobulin, a protein produced by the thyroid gland (and thyroid cancer cells). Studies have found that the presence of thyroglobulin preceded tumor recurrences by three to five years in 80% of patients. After removal of the thyroid, there should be no thyroglobulin present. If thyroglobulin is detected, this may signify the presence of tumors. Measurement of thyroglobulin through a simple blood test, also pioneered by Dr. LoGerfo in the 1970's, is now considered a standard of care today.

Low-risk patients may undergo neck ultrasound as well as thyroglobulin assays as part of their follow-up care. Both thyroglobulin and radioiodine scans, as well as PET/CT scans, are used in high-risk patients, mainly those with advanced, highly aggressive thyroid cancers. Although the use of thyroglobulin assays is standard throughout the world, the New York Thyroid Center is unique in that its surgeons, endocrinologists, and radiologists collaborate very closely in the care of each patient. "This collaboration not only makes for a better patient experience, but improves patient care," says Dr. McConnell. ■

Metabolic Surgery ~ continued from page 1

Incretins are hormones secreted by the gut after meals to help increase insulin secretion. In type 2 diabetics, incretins are either present in lower concentrations or they don't work well, explains Dr. Korner. After bypass surgery, there is a change in incretin secretion, as well as in other hormones related to appetite control and insulin sensitivity. "This may explain why gastric bypass is more effective than diet and exercise in helping people lose weight and controlling diabetes," she says. "When people lose weight by diet alone, a hormone secreted by the stomach (ghrelin) stimulates hunger, and ghrelin actually increases after losing weight through dieting. Over 90% of people regain their weight after a few years. After bypass surgery, however, ghrelin does not increase, so people do not experience increases in hunger. This helps people to keep their weight off." ■

THE DIABETES SURGERY STUDY

Dr. Inabnet and Dr. Korner are Principal Investigators at Columbia University Medical Center in the Global Randomized Prospective Study of Intensive Medical Management of type 2 Diabetes, with and without Gastric Bypass Surgery.

The study is a multicenter, randomized, controlled trial taking place at Columbia University Medical Center, the University of Minnesota, and the National Taiwan University. It will compare the effects of weight loss surgery (gastric bypass) and intensive medical management with outcomes after medical management alone. The study will measure HgA1 levels (an indicator of blood glucose control) and risk factors for cardiovascular disease, such as LDL cholesterol and blood pressure. The study is enrolling people with type 2 diabetes who have a BMI between 30 and 34.9 kg/m ^{2} (overweight but not clinically obese). Participants in the study are provided with free care for two years for diabetes management as well as the cost of surgery.

The study purposely includes Asian diabetics because type 2 diabetes occurs at a lower body weight among Asian populations, possibly due to genetic differences. Differences among ethnic populations, including Hispanics, Dominicans, and others, will also be studied within the trial.

Eligible participants must be between 35-67 years of age, have type 2 diabetes, have a BMI between 30-34.9 (40-75 pounds overweight), and be willing to be randomized to medical treatment or gastric bypass surgery with medical treatment for two years. Participants do not have to be patients at Columbia University Medical Center. ■

If you are interested in learning about participation in the diabetes surgery study, please contact the study coordinator at dssresearch@columbia.edu.

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