NEWYORK-PRESBYTERIAN

Digestive Diseases

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Fall 2004

Minimizing Trauma in Esophageal Cancer Surgery

Esophageal cancer, the cancer of the gastrointestinal tract that is currently showing the largest increase in frequency, is presenting new problems in the OR. "It used to be that we saw mostly squamous cell cancer, usually from smoking," noted Marc Bessler, MD. "Now that people are smoking less, we're seeing more adenocarcinoma of the distal esophagus, which is secondary to acid reflux."

During the past several years, surgeons at NewYork-Presbyterian Hospital/Columbia University Medical Center have started expanding their skills in laparoscopic surgery into a relatively new area: laparoscopic esophagectomy.

Laparoscopic esophagectomy is designed to remove a diseased lower esophagus. After years of experience with hundreds of laparoscopic stomach and esophageal operations, Dennis Fowler, MD, and Dr. Bessler both believe the improvements offered with minimal-access esophagectomy make it vastly superior to the more traditional methods, especially in early-stage esophageal cancers.

"Open esophagectomy, even under the best of circumstances, is a somewhat disabling surgery," noted Dr. Fowler.

According to Dr. Bessler, the procedure involves "5 or 6 small [$^1/_4$-in] incisions in the abdomen and 1 in the neck, rather than having to open the chest and

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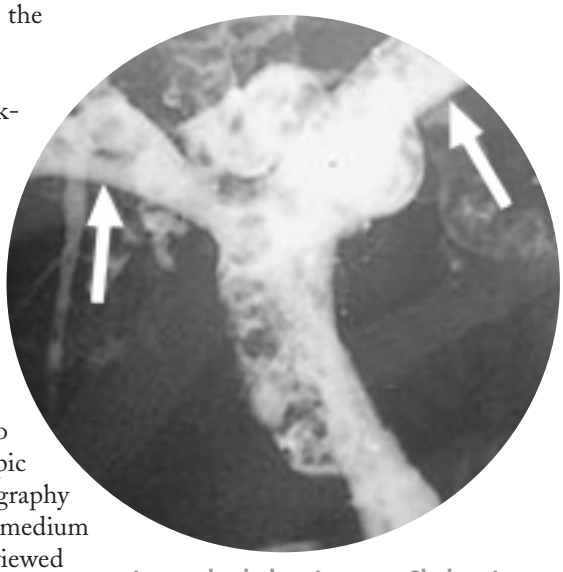
Scoping Technologies Revolutionize Diagnosis of Duct Disorders

To see more clearly into the pancreatobiliary ducts, Columbia and Weill Cornell physicians at NewYork-Presbyterian Hospital are taking ultrasound and endoscope technology where few other medical centers have gone before.

Older scoping technologies have been unable to access the pancreatobiliary ducts sufficiently to provide detailed images because the ducts are so narrow. This includes endoscopic retrograde cholangiopancreatography (ERCP)—in which a contrast medium is injected into the ducts and viewed with X-rays—or ultrasound, which, in this case, is used with the endoscope positioned outside the ducts.



A sample cholangioscopy. Cholangioscopy allows for better imaging of the pancreatobiliary ducts.

However, 2 technologies are being evaluated that allow physicians to get closer to the ducts and better treat both malignant and non-malignant disorders. The first is called intraductal ultrasound, in which a 2.2-mm probe is used to obtain images from inside the pancreatic or bile ducts; the second is cholangioscopy.

"We can actually put these probes into spaces the scopes won't go," said Peter D. Stevens, MD.

According to Dr. Stevens, the

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NewYork-Presbyterian
The University Hospital of Columbia and Cornell

Investigating New Options in the Treatment of Hepatitis C

Weill Cornell researchers at NewYork-Presbyterian Hospital are working on new protocols that may provide promising alternatives to current pharmacologic therapies for patients chronically infected with hepatitis C, laying the groundwork for future therapies among those who are treatment-naïve.

Patients who relapse after completing standard treatment (interferon/peginterferon and ribarvirin) for hepatitis C generally have limited options. Two such patients under the care of Gerond Lake-Bakaar, MD, restarted therapy. Shortly after their viral load dropped to undetectable levels, however, he opted to stop treatment, implementing a new technique called controlled or cyclical therapeutic interruption.

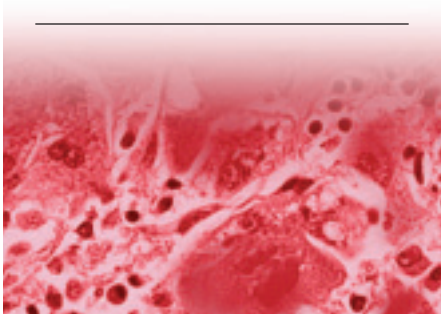
After acute hepatitis C infection, immune response fades and CD8 cells die, explained Dr. Lake-Bakaar. They leave a small number of virus-specific T cells, called memory cells, behind, which respond quickly and efficiently when the body is confronted with a secondary reinfection.

"The theory is that during the first infection the body made memory cells against hepatitis C, but these were inadequate for providing protective immunity," Dr. Lake-Bakaar said. "Reducing the viral load to undetectable levels with interferon and then allowing it to rise when therapy is interrupted simulates a secondary infection. When reexposed to the virus during this simulated secondary infection, memory cells mount a rapid, powerful attack on the virus before it can evolve and escape the immune attack. Each cycle hones immunity further until hopefully, a sustained virologic response is achieved."

This hypothesis is the basis for many studies conducted at the Center for the Study of Hepatitis C, which has one of the nation's most diversified clinical trials programs researching new treatments for the virus, according to Ira Jacobson, MD, Medical Director of the Center. The Center was established in 2000 as a cooperative endeavor of Rockefeller University and NewYork-Presbyterian Hospital/Weill Cornell.

"Reducing the viral load to undetectable levels with interferon and then allowing it to rise when therapy is interrupted simulates a secondary infection. When re-exposed to the virus during this simulated secondary infection, memory cells mount a rapid, powerful attack on the virus before it can evolve and escape the immune attack."

— *Gerond Lake-Bakaar, MD*



"We offer a combination of investigator-initiated trials, built on concepts developed at our site, and multicenter studies ranging from exploratory Phase I and II trials with novel agents to Phase III and postmarketing Phase IV studies," said Dr. Jacobson. "We initiate innovative trials to address specific issues and challenges, along with participating in multicenter studies sponsored by the biotech and pharmaceutical industries, which will lead to major therapeutic advances with new agents."

One such study for nonresponders combines consensus interferon with interferon gamma. Another combines novel agents like viral enzyme inhibitors with standard therapy. Dr. Lake-Bakaar is conducting a study of daily consensus interferon and ribavirin in patients who previously failed to clear the virus with pegylated interferon and ribavirin, and a large trial of treatment-naïve patients will compare the 2 pegylated interferons. Dr. Jacobson is initiating a study of daily consensus interferon and ribavirin in patients who come close to clearing the virus with standard therapy but do not eliminate every last trace of it.

The Center is also investigating the protective role of antibodies in chronic hepatitis C. The virus elicits a strong antibody response, but because most patients develop persistent chronic infection, researchers wonder whether antibodies leave the virus unaffected. Treatment of cryoglobulinemia, a condition that causes neuropathy and deposits in skin, kidneys, and nerves, provides a clue.

Cryoglobulins result when antibodies produced by B cells form complexes with the hepatitis C antigen. Cryoglobulinemia is often unaffected by interferon, but the symptoms respond to rituximab, a chimeric monoclonal antibody directed against the B-cell–specific antigen CD20.

Although rituximab causes a decline in B cells, immunoglobulin production, and anti–hepatitis C virus antibody titers, it is associated with steep increases of hepatitis C virus RNA levels in plasma. This reaction is not well understood, but it suggests that B cells and the immunoglobulins or antibodies

Future Therapies for HCV

Genome sequence–based	• Antisense oligonucleotides • Ribozymes • RNA interference
Viral enzyme inhibitors	• Protease • Helicase • Polymerase
Other	• IFN: albumin Consensus interferon Interferon gamma • RBV refinements (viramidine) IMPDH inhibitors • Immune modulation, including vaccines • Antifibrotic therapy

HCV, hepatitis C virus; **IFN,** interferon; **IMPDH,** inosine monophosphate dehydrogenase; **RBV,** ribavirin; **RNA,** ribonucleic acid

they produce may play a role in clearing the virus from plasma.

Another puzzle emerges from this reaction. Patients with B-cell deficiencies have more progressive hepatitis C disease, yet based on a small number of reported cases, they respond well to interferon.

"These patients may progress faster because without antibodies binding to the virus, there's more free virus available to invade new liver cells," said Dr. Lake-Bakaar. "Yet without antibodies, the virus doesn't have to change continually, so there are fewer variants."

Dr. Lake-Bakaar's team will examine viral sequences after rituximab to figure out how viral evolution changes without immune pressure. "These patients will hopefully respond better to therapy after rituximab," he said.

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NewYork-Presbyterian Digestive Diseases
is a publication of the Digestive Diseases Center of NewYork-Presbyterian Hospital. The Digestive Diseases Center is at the forefront of research and practice in the areas of gastroenterology; GI surgery; and liver, bile duct, and pancreatic disorders. NewYork-Presbyterian Hospital/Columbia University Medical Center and NewYork-Presbyterian Hospital/Weill Cornell Medical Center are respectively affiliated with Columbia University College of Physicians and Surgeons and the Weill Medical College of Cornell University.

Ensuring Accuracy in the Testing of Motility-Related Disorders

Motility-related disorders of the gastrointestinal (GI) tract often present problems to both primary care physicians and gastroenterologists. Despite recent interest in GI motility (also known as "functional") disorders such as gastroparesis, dyspepsia, diarrhea, constipation, and irritable bowel syndrome (IBS) within the research community and pharmaceutical industry, these disorders remain poorly understood and frequently misdiagnosed. Few effective treatments exist, and specialists still debate the exact characteristics and symptoms of many of the disorders, which affect between 60 and 70 million people in the United States. With diagnosis and treatment costs expected to exceed $10 billion this year alone, recent research efforts have focused primarily on new diagnostic procedures and systems.

Physicians at the new Gastrointestinal Motility Center at NewYork-Presbyterian Hospital/Weill Cornell Medical Center are at the forefront of this effort. The Center, which opened in May with the support of the C.V. Starr Foundation, operates based on a "hands-on approach" to testing and treatment, according to Arthur D. Harris, MD, director of the facility. It was established so that the Hospital could lead clinical trials of promising medications for a variety of GI motility disorders and be among the first to implement new diagnostic technologies.

"It's a quality assurance issue," said Dr. Harris. "When I see patients who've been tested and diagnosed elsewhere, it's not uncommon that I can't make heads or tails of their results because they were performed incorrectly or incompletely. If a patient gets referred here, doctors can feel more confident in the results, thereby avoiding additional patient anxiety by preventing the need for repeat testing."

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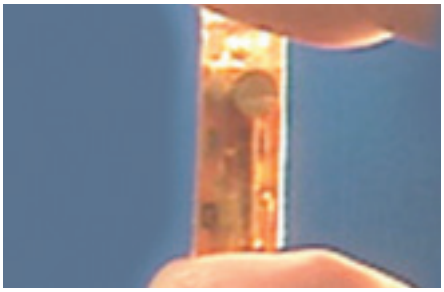

Photo courtesy of Medtronic Inc.

The Motility Center at NewYork-Presbyterian Hospital/Weill Cornell Medical Center plans to offer wireless pH monitoring within the next year. In this procedure, sensors (shown above) are placed endoscopically in the GI tract to produce the same results as 24-hour, conventional pH monitoring.

GI motility is a complex process, coordinated by the enteric nervous system, that facilitates propulsion of foodstuffs through the digestive tract while maximizing nutrient absorption. While the cause of many motility-related disorders remains unknown, these disorders are a substantial source of morbidity leading to frequent absenteeism from work and utilization of healthcare resources. Whereas endoscopy allows physicians to view the anatomy and structure of the GI tract, motility studies reveal how it functions.

"I compare it to when you go to buy a car," said Dr. Harris. "When you sit in the seats and look the vehicle over in the showroom, that's akin to visual studies like endoscopy. But when you take it to a mechanic to check how the engine runs, that's like the functional motility testing I do."

The Center offers the latest in testing and diagnostic equipment. These include esophageal manometry, which measures the strength and function of the esophagus and can help diagnose disorders such as achalasia and scleroderma, or evaluate function before or after esophageal surgery. According to Dr. Harris, 24-hour pH monitoring, which measures the degree of esophageal acid reflux, can assess if heartburn symptoms correlate with changes in pH and identify if acid reflux is the cause of less common complaints, such as noncardiac chest pain, chronic laryngitis, and unexplained cough. For patients with chronic constipation or fecal incontinence, anorectal manometry measures the various components of the anorectal sphincter complex, and whole-gut transit time measures the time it takes for radiopaque markers to move through the lower GI tract.

While these tests can be relatively time-consuming, they are vital for the proper diagnosis of the complicated symptoms that often are the hallmark of GI motility disorders. The Center plans to offer wireless pH monitoring within the next year. In this procedure, sensors are placed endoscopically in the GI tract to produce the same results as 24-hour, conventional pH monitoring. "And the

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Improving Outcomes in Pancreatic Cancer

The success rate in treating pancreatic cancer has always been abysmal. "Nothing really has worked," said John D. Allendorf, MD. "We have response rates in the 10% to 15% range and maybe 20% to 25% with gemcitabine," a newer chemotherapy agent that has shown promise in pancreatic cancer treatment.

Now, a new chemoradiation protocol developed at the Herbert Irving Comprehensive Cancer Center (HICCC) has increased the surgical success rate in patients with locally advanced pancreatic tumors that formerly were inoperable. The protocol, developed by Robert L. Fine, MD, and his team, involves treatment with a combination of 3 chemotherapy drugs—gemcitabine, docetaxel, and capecitabine—followed by combination therapy consisting of gemcitabine and abdominal radiation. Six weeks after completion of radiation, patients undergo surgery to remove their tumors.

In a study presented at the 6th World Congress of the International Hepato-Pancreato-Biliary Association in Washington, DC, this past June, a group from the HICCC led by Dr. Allendorf reported on 16 pancreatic cancer patients who underwent surgery following the chemoradiation combination. These were patients with locally advanced disease who could not be treated with surgery before chemoradiation. "The first impressive thing was that during the 5 months on the protocol, none of the patients had disease progression, and in many cases the tumor shrank," said Dr. Allendorf. "The median survival for patients with locally unresectable tumors is probably about 8 to 10 months."

> "If you can take that 30% population of patients and get tumors to shrink just enough so that you can remove the tumor, you could potentially triple your surgical impact on the disease."
>
> —John D. Allendorf, MD

According to Dr. Allendorf, they were able to remove the tumors in 12 (75%) of the 16 patients. Two of the 4 patients who could not undergo surgery had tumors that were too advanced locally, and the other 2 had disease in their liver that had not been picked up during computed tomography.

All 12 patients whose tumors were resected survived the surgery, which, explained Dr. Allendorf, "tends to be a

see Pancreatic Cancer, page 6

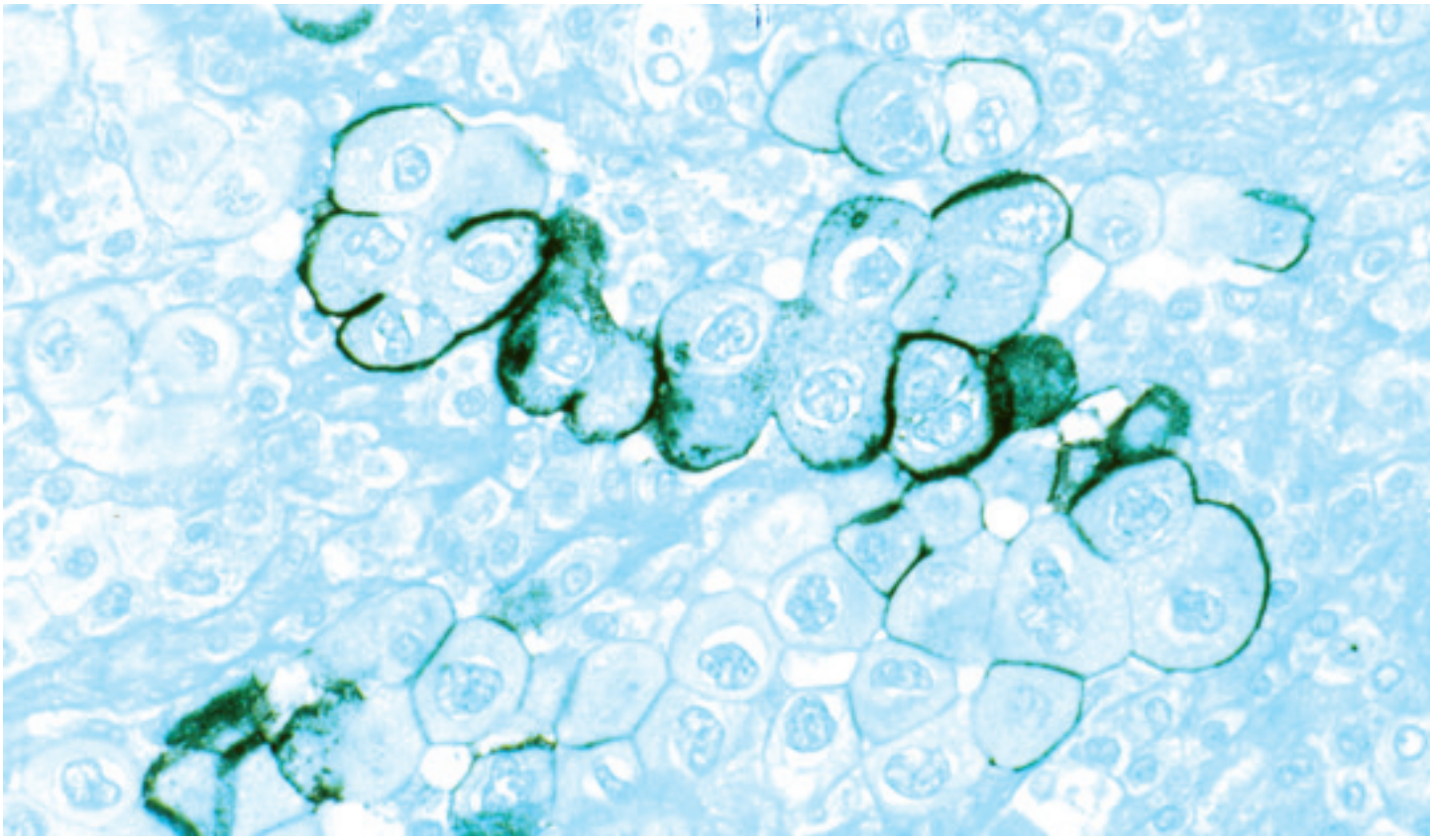

Photo courtesy of the National Cancer Institute.

Human tumor cells from the pancreas stained with an immunocytochemical stain.

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patient doesn't have a catheter down their nose for 24 hours," Dr. Harris said.

"I often tell patients that it's never 1 individual test that gives the answer," he continued. "There are many things that can trigger symptoms in a given individual, whether it's a systemic disease, functional disorder, diet, or superimposed and/or coexistent psychological issues. You end up using complementary tests to help make a proper diagnosis."

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Continuing Medical Education Seminars

The following is a partial list of CME programs offered through NewYork-Presbyterian Hospital. To register, or for more information, please visit www.columbiacme.org or www.med.cornell.edu/education/cme.

Contemporary Evaluation and Management of Reflux and Swallowing Disorders

DATE: Saturday, November 6
LOCATION: NewYork-Presbyterian Hospital/Columbia University Medical Center, New York City

Obesity: Understanding the Biological and Psychological Dimensions of the Worldwide Pandemic

DATE: Friday, November 12
LOCATION: Morgan Stanley Childrens Hospital of New York-Presbyterian, 3959 Broadway, New York City
Full day, maximum of 8 category 1 credits

Update in Gastroenterology, Hepatology, and Nutrition

DATE: Friday and Saturday, December 3 and 4
LOCATION: Weill Medical College of Cornell University, Uris Auditorium, New York City
Jointly sponsored by Columbia University College of Physicians and Surgeons and Weill Medical College of Cornell University.
For more information, visit www.columbiacme.org.

Pancreatic Cancer

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very challenging operation. "They've had all this radiation therapy to their abdomen, and the tumors are usually larger than ones we generally operate on." Moreover, the portal vein had to be reconstructed in 4 of the patients and the mesenteric artery replaced in 2 others.

"What we look at is the margins of our specimen; is there any tumor on the margins?" he said. In 10 (83%) of the 12 patients whose tumors were removed, the margins were negative, he said, "which is pretty remarkable."

The outlook for pancreatic cancer patients is generally poor. Of those who present with the disease, about 55% have tumors that have metastasized and so are not candidates for surgery. Overall, 15% have tumors small enough to be resected surgically. The target population for the chemoradiation protocol is the remaining 30% of patients with locally advanced tumors that cannot be operated on without neoadjuvant therapy, such as the protocol developed by Dr. Fine.

Suggested Reading

NewYork-Presbyterian/Columbia physicians have led or been involved in numerous studies investigating pancreatic cancer and related diseases and authored or coauthored several articles on the topic. Among them:

Stevens PD, Lightdale CJ. The role of endosonography in the diagnosis and management of pancreatic cancer. *Surg Oncol Clin N Am. 1998;7:125-133.*

Larghi A, Verna EC, Stavropoulos SN, Rotterdam H, Lightdale CJ, Stevens PD. EUS-guided trucut needle biopsies in patients with solid pancreatic masses: a prospective study. *Gastrointest Endosc. 2004;59:185-190.*

Nord HJ, Brady PG, Lightdale CJ, Reddy RK, Eisen GM, Dominitz JA, Faigel DO, Goldstein JA, Kalloo AN, Petersen BT, Raddawi HM, Ryan ME, Vargo JJ 3rd,Young HS, Fanelli RD, Hyman NH, Wheeler-Harbaugh J; American Society for Gastrointestinal Endoscopy. Diagnostic laparoscopy guidelines for clinical application. *Gastrointest Endosc. 2001;54:818-820.*

Goldstein MJ, Toman J, Chabot JA. Pancreaticogastrostomy: a novel application after central pancreatectomy. *J Am Coll Surg.. 2004;198:871-876.*

Sherman WH, Fine RL. Combination gemcitabine and docetaxel therapy in advanced adenocarcinoma of the pancreas. *Oncology. 2001;60:316-321.*

"If you can take that 30% population of patients and get tumors to shrink just enough so that you can remove the tumor, you could potentially triple your surgical impact on the disease," Dr. Allendorf said. Increasing the potential for surgical success is just what the Columbia team has done.

"People talk about a 20% to 30% resectability rate with neoadjuvant chemotherapy," said Dr. Allendorf, "but this is the first study that I'm aware of where we had a resectability rate of 75%. So, yes, it's very encouraging."

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Esophageal Surgery

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abdomen." The surgeons start in the abdomen and use a laparoscope to guide them through the chest to the proximal third of the esophagus. Then they remove the esophagus through a small neck incision and replace it with a tube created from a portion of the stomach. The tube is reattached to the still-intact upper portion of the esophagus in the neck.

Although the surgery takes a bit longer (4 to 5 hours instead of 3 to 4), the trauma patients experience during the procedure is significantly less. Patients generally leave the hospital in 5 days instead of 10. "We can see what we're doing, so there's not as much risk of injury, and there's less bleeding than with open trans-hiatal esophagectomy," explained Dr. Bessler. "We don't know for sure, but by causing less trauma to the body, we may be allowing the immune system to stay in better shape to fight off any residual tumor."

Neither doctor can find any negatives to the laparoscopic procedure in patients with stage I or II esophageal cancer. In the latter group, according to Dr. Bessler, "we'll have them undergo pre-op chemotherapy and radiation therapy before the surgery; that way, we shrink the tumor and only treat the diseased esophagus and not the stomach, as would be the case with radiation after surgery."

> **"Open esophagectomy, even under the best of circumstances, is a somewhat disabling surgery."**
>
> *—Dennis Fowler, MD*

However, the researchers are still looking into whether the procedure can "remove as many lymph nodes," said Dr. Fowler. The Ivor-Lewis technique—which requires large incisions in both the chest and abdomen—may provide more effective harvesting of lymph nodes in more advanced cancers than does laparoscopic esophagectomy. For larger tumors or tumors of the proximal esophagus, thoracoscopy in combination with laparoscopy may be used.

Still, both doctors believe laparoscopic esophagectomy is a viable alternative for many patients and urge their colleagues to seek consultations whenever they are considering esophageal surgery. Dr. Fowler acknowledges that for more advanced cancers, the Ivor-Lewis technique is still recommended. His concern is that too many surgeons may be using it, or the open trans-hiatal technique, unnecessarily.

"The only patient for whom we probably wouldn't do laparoscopic esophagectomy is one with cancer that has gone into the full thickness of the esophagus or in whom it has metastasized," added Dr. Bessler. "If in the former case the tumor shrank to a manageable size after radiation and chemotherapy, laparoscopy might still be a viable option."

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New Technologies

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sharper images are especially helpful where there are strictures or masses of an indeterminate nature and when there are malignancies. "We hope that intraductal ultrasound will help us diagnose and stage the cancers earlier and more effectively," he added. "It will get a patient to surgery faster or avoid unnecessary surgery."

Dr. Stevens—along with Stavros Stavropoulos, MD, and Charles Lightdale, MD—has been working with Olympus, the camera manufacturer, to design smaller, nimbler probes, as well as software to better analyze the results. Earlier this year, at the Digestive Disease Week meeting in New Orleans, he presented a paper describing a prototype technology that features production of a 360-degree image with Doppler analysis. In a study of 26 patients, he found it allowed for easier anatomic interpretation and excellent Doppler analysis of vascular flow.

> **"We're just beginning to investigate the capacity of the software to improve our diagnosis."**
>
> *— Peter D. Stevens, MD*

In another paper coauthored with Dr. Stavropoulos, Dr. Stevens described new software that allows reconstruction of 3-dimensional ultrasound images. In a study of 20 patients, he evaluated 7 biliary strictures, 5 dilated bile ducts, 2 cases of choledocholithiasis, 1 ampullary adenoma, 1 case of idiopathic pancreatitis, 1 resected gallbladder adenoma (for surveillance), and 3 cases of biliary colic. In each case, the 3-dimensional software considerably increased the appreciation of anatomic structures.

"We're just beginning to investigate the capacity of the software to improve our diagnosis," he said.

Savreet Sarkaria, MD, another co-author of the second paper, now specializes in pancreatic and biliary disease and

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performs ERCP, intraductal ultrasound, cholangioscopy, and other procedures.

"There's a common misperception that intraductal ultrasound is too difficult, adds too much time, or requires a sphincterotomy," Dr. Sarkaria said. "None of those are true. It's very easy to implement and only adds a couple of minutes to the procedure."

Standard ERCP is usually sufficient to diagnose gallstones in the bile ducts, which show up as filling defects on the X-ray images after injection of contrast. However, Dr. Sarkaria explained, "intraductal ultrasound can increase the diagnostic sensitivity and specificity of ERCP. This can help you pick up tiny stones or biliary sludge. It gives you a very fine, detailed view of the ducts."

According to Dr. Sarkaria, although strictures show up with ERCP as narrowings in the ducts, ERCP does not provide information about the walls of the ducts or the surrounding anatomic structures. "Sometimes intraductal ultrasound can help characterize the nature—benign or malignant—and extent of the stricture, and even help better target intraductal biopsies," she said.

Drs. Stevens and Sarkaria also perform cholangioscopy, a procedure that requires 2 skilled endoscopists. A cholangioscope is essentially a scope within a scope. The outer scope is called the "mother" scope, and the inner is called the "baby" scope. The technology allows better imaging and, ultimately, improved diagnostics. In some situations, Dr. Sarkaria said, this direct visualization can be vital, such as in electrohydraulic lithotripsy, in which shock waves are used to disintegrate large intraductal stones.

"The stone is crushed under direct observation with the endoscope," she said. "It's not safe to try to break these stones without directly viewing them."

As useful as both cholangioscopy and intraductal ultrasound can be, however, "you don't need them that often," Dr. Sarkaria said. She estimated that in only about 5% of cases are such specialized technologies necessary. "When needed, it's nice to have the extra dimension of visualization they provide."

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Important news from the Digestive Diseases Services Center of NewYork-Presbyterian Hospital, leading the way in treatment and research in gastrointestinal, liver and bile duct, pancreatic, and nutritional disorders.