## NEWYORK-PRESBYTERIAN

# Digestive Diseases

Affiliated with COLUMBIA UNIVERSITY COLLEGE OF PHYSICIANS and SURGEONS and WEILL MEDICAL COLLEGE OF CORNELL UNIVERSITY

Spring 2006

### New Visualization Techniques for ERCP

B ased on the results of their groundbreaking clinical investigations, Columbia researchers at NewYork-Presbyterian Hospital believe intraductal ultrasound is a viable option in critically ill patients undergoing endoscopic retrograde cholangiopancreatography (ERCP).

"Performing traditional ERCP in critically ill patients is difficult because they are usually intubated on ventilators to support respiration and attached to multiple devices and medication drips to monitor and support blood pressure and other functions, which limits mobility," said Stavros N. Stavropoulos, MD.

In the past, according to Dr. Stavropoulos, physicians transferred such patients, along with monitoring equipment, to an operating room, where traditional ERCP would require general anesthesia and a fluoroscopy unit (the current gold standard for visualization).

"It was kind of a logistic nightmare," said Dr. Stavropoulos. "There were also some safety issues getting the patient from the ICU to the OR bed, then back to [the] ICU while unconscious."

Because the use of ERCP with intraductal ultrasound obviates the need to move the patient, the procedure may be lifesaving. According to Peter Stevens, MD, each year, approximately 3 or 4 patients at the hospital undergo ERCP with intraductal ultrasound for cancer

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## Researchers Enhance Hepatic Resection Procedures

olumbia and Weill Cornell surgeons at NewYork-Presbyterian Hospital continue to make strides in hepatic resection, carefully selecting patients and using the latest technology as they perform increasingly sophisticated surgical procedures in an effort to improve patient outcomes in liver diseases such as cirrhosis.

"Overall, research is making liver resection safer and making much more complex resections possible," said Jean C. Emond, MD. "The blending of the better selection of

Photo of a resected liver: Columbia and Weill Cornell surgeons at NewYork-Presbyterian Hospital use the latest technology and patient selection techniques to improve outcomes in liver diseases such as cirrhosis.

transplant patients and improvements in liver surgery creates the optimal conditions for solving really difficult problems."

"Liver resections have become very technical and demanding operative procedures done by specialized surgeons," added Milan Kinkhabwala, MD.

The procedure is performed when a piece of the liver is damaged; for example, in connection with a tumor. The damaged portion of the organ can be removed safely, and the liver can grow back if the remaining tissue is healthy. With new technologies, surgeons are able to remove up to 75% of the liver, letting the

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## **Surgeons Seek Improved Outcomes** With Restorative Proctocolectomy

urgeons have long viewed restorative proctocolectomy (RP) as a cure for ulcerative colitis. Historically, RP involved complete removal of the diseased colon and nearly all of the rectum as well as stripping of the inner lining of any remaining rectum. To allow for defecation, surgeons then hand sewed an anastomosis, forming a loop of small intestine to create a reservoir, or pouch, close to the anal opening.

Since the mid-1980s, however, surgeons have preferred following RP with stapled anastomosis, which leaves behind 1 to 2 cm of rectal cuff and results in shorter operating times and better postoperative sphincter function. Concerned about the development of

pouch adenocarcinoma in patients undergoing either procedure, Weill Cornell researchers at NewYork-Presbyterian Hospital reviewed all reported cases of patients who developed the disease after RP, as well as 3 additional cases treated at the Hospital. Their findings were published in Colorectal Disease (2005;7:537).

"The procedure has been done for about 30 years now, and a theoretical risk exists for developing colon cancer over the long term," said Sang Lee, MD.

According to Dr. Lee, even though the colon and the rectum are removed, a risk of adenocarcinoma exists because microscopic residual mucosal cells are left behind up to 20% of the time; these cells can become malignant. However, after a

Finding an experienced surgeon is crucial for the success of RP followed by anastomosis. Inexperienced surgeons tend to leave behind much longer portions of the rectum, increasing the patient's risk of developing cancer.

#### Table. Factors Common to Patients Who Have Developed Pouch-Related Cancers

- Long (>10-15 y) history of antecedent ulcerative colitis
- Dysplasia or cancer in the excised specimen, especially in the rectum
- Poor postoperative surveillance
- Severe or delayed presentation of pouchitis

Note: Any patient presenting with nonspecific symptoms of abdominal discomfort and anal or sacral pain should be closely monitored.

review of the literature, Dr. Lee and his colleagues found an extremely low risk of cancer in RP patients, regardless of the type of anastomosis they received.

In addition to the 3 cases at NewYork-Presbyterian/Weill Cornell, 16 cases of adenocarcinoma after RP were reported in medical literature. Of these 16, 10 patients underwent RP followed by hand-sewn anastomosis, whereas 5 patients underwent a stapled anastomosis. In one case, there was no mention of the type of anastomosis performed. The higher incidence of adenocarcinoma in the hand-sewn group is most likely the result of the longer follow-up time and greater number of patients who have undergone this technique in its early development, said Dr. Lee.

Researchers are beginning to see more cancer cases developing now, according to Dr. Lee. He and his team believe that the risk of developing cancer seems to be associated with a diagnosis of dysplasia at the time of RP (see Table for risk factors associated with pouch-related cancers). In cases in which dysplasia or malignancy is suspected preoperatively, RP with mucosectomy and hand-sewn anastomosis probably should be performed with consideration given to a wide lymph node dissection in the affected region.

Finding an experienced surgeon is crucial for the success of RP followed by anastomosis, said Dr. Lee. Inexperienced surgeons, he said, tend to leave behind much longer portions of the rectum, increasing the patient's risk of developing cancer. In Dr. Lee's literature review, some of the patients who developed cancer were lost to follow-up for several years because yearly monitoring was not standard at the time. Follow-up needs to be performed by someone who is experienced with RP procedures, according to Dr. Lee.

Monitoring patients for adenocarcinoma after the staple procedure is relatively easy because the remaining small cuff of colon tissue can be biopsied. In contrast, the hand-sewn technique involves stripping the mucosal lining and then bringing the pouch over this stripped area, making it difficult to see and monitor. Surveillance strategies for the 2 groups may differ on the basis of the locations



In addition to studying the long-term outcomes of patients receiving open RP surgery, Weill Cornell researchers are investigating the benefits of laparoscopic RP with staple anastomosis.

in which subsequent cancer is most likely to develop. In Dr. Lee's review, researchers found that 6 of 12 patients in the hand-sewn anastomosis group developed cancer in the pouch mucosa, whereas those in the stapled anastomosis group developed cancer in the anal transitional zone.

In addition to studying the long-term outcomes of patients receiving open RP surgery, Weill Cornell researchers are investigating the benefits of laparoscopic RP with staple anastomosis, said Dr. Lee. This procedure is less invasive while having the same outcomes as open surgery, which affords the hope of even better management of ulcerative colitis, he added.

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### Case Study: **Incorporating EUS Technology** Into Gastrointestinal Diagnosis

The Case

55-year-old, otherwise asymptomatic woman was found to have elevated liver chemistries during a routine examination by her physician. A follow-up sonogram showed a small shadow on her pancreas. Subsequent CT scan and magnetic resonance studies revealed the presence of a small, complex cyst in the head of the pancreas. The physician referred the patient to the Jay Monahan Center for Gastrointestinal Health at NewYork-Presbyterian Hospital/Weill Cornell Medical Center for evaluation of the lesion using endoscopic ultrasound (EUS).

The EUS procedure actually disclosed 2 small cysts in the head of the pancreas, one measuring approximately 1 cm in diameter and the other, 6 mm. Fine-needle aspiration (FNA) was performed, and the cytology showed the cells to be glandular with mucus globules, indicating that the cysts were mucin-producing. There was also some atypia, a sign that the cells might be turning cancerous.

A test for carcinoembryonic antigen (CEA) in the cystic fluid showed an abnormally high elevation, 2620 ng/mL, signifying that the cysts were either already malignant or were more aggressive and could rapidly turn malignant. The differential diagnosis was a mucinous cystic neoplasm or intraductal papillary mucinous tumor (IPMT). The Monahan Center team—led by Mark Pochapin, MD—recommended surgery. Treatment recommendations are ultimately based on a patient's cytology results and cyst fluid analysis results, as well as underlying medical condition and age.

"In the case of this patient, we were able to show through EUS and fine-needle aspiration that the cyst was already turning cancerous."

-Mark Pochapin, MD

A Whipple procedure was performed by Michael D. Lieberman, MD. First performed in 1935 by Allen Whipple, MD, at Columbia Presbyterian Hospital, now known as NewYork-Presbyterian Hospital/Columbia University Medical Center, the operation is an extensive procedure that involves removing the head of the pancreas, the duodenum, the antrum of the stomach, the distal bile duct, and the gallbladder. Once these organs are removed, the remaining portions of the pancreas, stomach, and bile duct are attached to the intestine.

In this patient, pathology showed the cystic lesion to be an IPMT with some focal, mild to moderate dysplasia, indicating that while this was a neoplastic growth, it was not yet malignant. In addition, all of the margins were negative and the main pancreatic duct was not involved.

The patient's postoperative recovery was rapid and without complications.

Labs drawn 10 months after the procedure showed that the patient's liver chemistries had returned to normal, suggesting that they might have been elevated originally because mucus from the tumor was clogging the main bile duct, not allowing liver enzymes to pass through.

#### **Discussion**

EUS, which uses a special endoscope with an ultrasound transducer at the tip, gives gastroenterologists a close-up view of lesions and other abnormalities in the gastrointestinal (GI) tract. It allows evaluation not only of the lesions but also of surrounding tissue and has become an important tool for diagnosing GI abnormalities and for staging cancers. NewYork-Presbyterian Hospital has been among the leaders at integrating this technology into diagnostic procedures. Many patients found to have small pancreatic cysts are followed to see if any changes occur, rather than undergoing surgery. If the cyst becomes larger, if the cystic fluid shows evidence of progression, or if pain or pancreatitis develops, the patient is reevaluated for possible surgical intervention.

"In the case of this patient," Dr. Pochapin said, "we were able to show through EUS and fine-needle aspiration that the cyst was already turning cancerous." So, a Whipple procedure was recommended even though the lesions were relatively small.

"These are extremely difficult cases in which to make a decision to operate," added John Chabot, MD. "I probably would have recommended resection also, but it is by no means an obvious conclusion. Side branch IPMN carries less risk of malignancy than main duct IPMN. If that could be determined preoperatively it would argue against surgery. The marked elevation of CEA, however, would be the strongest evidence to proceed with surgery. In an 80year-old, I would say surgery should be discouraged with this set of findings."

However, in this younger patient, the cysts' location in the head of the pancreas dictated the selection of the Whipple over other surgical options, according to Dr. Lieberman. If the cysts

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# State-of-the-Art Medical Simulation Crucial For Surgical Training in Digestive Diseases

Interactive computer simulation is an integral part of training surgeons and physicians at NewYork-Presbyterian Hospital on gastroenterologic procedures. The Hospital has been among the leaders in the country at employing this innovative training technology, with 4 computer-based virtual simulators in the surgical department to learn and hone technical skills. Through the use of this technology, NewYork-Presbyterian Hospital has been able to develop some of the most highly skilled GI surgeons in the country.

"Simulators are valuable for teaching surgical residents and gastrointestinal fellows specific techniques and procedures," said Dennis Fowler, MD. "We want surgery and endoscopy simulators to do for surgeons what flight simulators do for pilots." Flight simulators train pilots to fly under a variety of conditions, he explained. They also document the individual's competency.

Surgery simulations in the field of digestive diseases consist of computergenerated images that recreate what's seen through an endoluminal endoscope or a laparoscope. The computers are capable of simulating full endoscopy, complete endoscopic retrograde cholangiopancreatography (ERCP), bronchoscopy, colonoscopy, and upper endosocopy, according to Dr. Fowler. Surgery simulators are part task trainers, meaning they do not simulate a complete operation; rather, the technology generates specific tasks such as the application of surgical clips or the cutting of tissue during dissection of the gallbladder.

"This technology helps surgical residents develop the hand-eye coordination necessary for minimal access surgery," noted Mark Hardy, MD. Such skills need to be practiced and tested on simulators, rather than on patients. "It's inappropriate to practice on patients, which not only takes much longer than simulation, but also increases the cost of healthcare delivery."

The Hospital simulators will ultimately

be used to assess competency throughout the duration of an individual practitioner's career, said Dr. Fowler. Another use of simulation training is to assist teams of people in the operating room, including anesthesiologists, nurses, and gastrointestinal surgeons, to optimize patient safety and efficiency. This training will improve the performance of the team by simulating actual events in a mock operating room environment. Regardless of their application, how much training surgeons need on simulation devices before performing an actual procedure varies on an individual basis.

still has room for improvement, not only in surgery but also in medicine and pediatrics. For example, medical simulation should use 3-dimensional visualization as much as possible. The technology also needs to be more tactile, while providing sensory feedback. Combining computer simulation with medical mannequins will make training even more realistic, said Dr. Hardy.

Simulators currently have 2 deficiencies, according to Dr. Fowler. The software and interface have not yet been developed to the point where students can simulate complete operations, and

"Simulators are valuable for teaching surgical residents and gastrointestinal fellows specific techniques and procedures. We want surgery and endoscopy simulators to do for surgeons what flight simulators do for pilots."

-Dennis Fowler, MD

"You can't just define how many sticks or passes someone should make before being considered qualified," said Dr. Hardy. "Some students will succeed after 10 tries. Then there will be individuals who never do it and don't belong in the field in which they are practicing."

To ensure skill goals are met, simulators need to be an intrinsic part of a larger curriculum for training practitioners, according to Dr. Fowler. The American Board of Surgery is working toward a defined curriculum for surgery trainees, and this curriculum should be available in 2 or 3 years. At NewYork-Presbyterian Hospital, a curriculum is already in place for training in laparoscopic surgery.

Although simulation is a crucial part of training physicians, the technology

researchers have not completed validation studies indicating that various types of simulators improve performance. "It's still a work in progress," he explained.

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#### **ERCP**

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indications and for indeterminate biliary strictures. However, an additional ERCP with fluoroscopy (scheduled for a later date when patients are feeling better) is indicated for most patients.

"Intraductal ultrasound won't replace fluoroscopy," said Dr. Stevens. "But I think the procedure is very important for this small number of patients. You're able to take care of these very ill patients in an efficient manner, and the hospital is able to treat a wider range of people."

Dr. Stevens said that the only other way to treat patients who require a biliary procedure and cannot be moved to the OR is to insert a guidewire and, without visualization, remove bile using a catheter. This procedure involves a risk of the physician removing bile from the wrong duct.

ERCP with intraductal ultrasound allows practitioners to confirm that the guidewire is inserted properly through the endoscope and into the bile duct (rather than into the pancreatic duct); this is a consideration because the bile duct and pancreatic duct share a common orifice through which the guidewire must be maneuvered, explained Dr. Stavropoulos. Although intraductal ultrasound has some blind spots that are not associated with fluoroscopy, practitioners are trained to recognize landmarks differentiating the 2 ducts. There are also other subtle indicators that the wire has entered the pancreatic duct. For example, tactile resistance to wire insertion is encountered earlier when the wire is unintentionally guided into the pancreatic duct than when it successfully has entered the bile duct.

Additionally, this procedure allows the practitioner to identify structures within the bile duct that ultrasound performed outside the abdomen cannot. "Intraductal ultrasound won't replace fluoroscopy. But I think the procedure is very important for this small number of patients. You're able to take care of these very ill patients in an efficient manner, and the hospital is able to treat a wider range of people."

-Peter Stevens, MD



Intraductal ultrasound can detect how many stones are present, where they are located within the duct, and how long a stent is needed for treatment, said Dr. Stavropoulos. The procedure also can assess if a tumor is present.

Drs. Stavropoulos and Stevens published data on 4 patients who successfully underwent ERCP with intraductal ultrasound (Endoscopy 2005;37:389-392). The Columbia researchers performed cannulation endoscopically at the patients' bedside using a sphincterotome and a guidewire. Intraductal ultrasound was then used to confirm the location of the wire within the common bile duct before endoscopic sphincterotomy or stent placement were performed. The technique was successful in all 4 patients.

One drawback of intraductal ultrasound is that the practitioner is unable to make immediate adjustments, said Dr. Stevens. For example, if physicians have trouble removing a stone or the stone comes out with the guidewire still in place, they need the continuous visualization that fluoroscopy provides to complete the procedure. He further clarified that ERCP with intraductal ultrasound also requires knowledge of how to cannulate the bile duct with a guidewire and interpret intraductal images without fluoroscopy.

Over the next several months, Drs. Stavropoulos and Stevens plan to extend their study; their goal is to demonstrate in a sufficient number of patients—at least 40 to 50-an anticipated high success rate (80%-90%) for this procedure, with a low complication rate (ie, similar to that associated with traditional ERCP in critically ill patients).

"These data would be necessary before we can recommend wider application of this procedure as an alternative to traditional emergency ERCP in an OR," said Dr. Stavropoulos. "Right now this is an investigational procedure that needs to be looked at further."

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remaining portion of the organ regenerate. However, if the liver is diseased with cirrhosis, for example, its ability to regenerate is impaired.

"Liver resection needs to be performed with caution, while considering several parallel issues at the same time," said Dr. Emond. With cirrhotic patients, he added, physicians must determine whether overall health is good enough and whether the course of cirrhosis is early enough in its progression for the individual to recover without liver failure, he explained.

Doctors must also consider whether cancerous tumors, which can develop after the onset of cirrhosis, can be treated without open surgery. "Treating liver tumors without opening the person up for a major liver resection is becoming more common," said Dr. Emond.

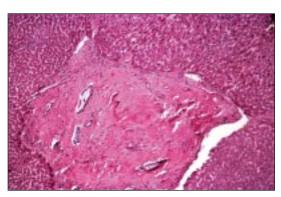
Radiofrequency ablation, which involves coagulation of the tumor using heat under direct ultrasound or computed tomography, is an option. Another is chemoembolization, involving the insertion of a catheter under X-ray guidance into the tumor to deliver chemotherapy and drugs that block the flow of blood to diseased tissue. Researchers are also using laparoscopy to remove tumors in patients with cirrhosis.

"These methods help to avoid the major shock of open surgery that patients with cirrhosis can't handle," explained Dr. Emond. If the tumor is small and localized, minimally invasive surgery may be an option.

If the cirrhosis has led to the beginning of liver failure and there are tumors in the organ, then transplantation is the best treatment option. If, however, liver function is fairly stable for example, if it is considered likely that the patient can live 5 years without transplant—liver resection may be preferable. As with any cancer patient, a person who undergoes liver resection for a tumor needs to be carefully monitored afterward with sequential computed tomography scans and blood tests to measure tumor markers. Furthermore, patients need to have their general liver function monitored,

"Liver resections have become very technical and demanding operative procedures done by specialized surgeons."

-Milan Kinkhabwala, MD



A micrograph of a cirrhotic liver. New technology has made hepatic resection procedures for patients with cirrhosis and other liver diseases safer and more effective. Still, a skilled surgeon is vital.

because if their cirrhosis happens to progress, they may be candidates for transplantation. Overall, new procedures such as coagulation used to seal liver tissue and limit bleeding are becoming useful in both open surgery and laparoscopy, as they reduce bleeding and streamline the surgical process.

According to Dr. Kinkhabwala, another important tool is state-of-the-art ultrasonography, which enables surgeons to map circulation of the liver during resection, plan operations, and remove diseased portions without compromising the rest of the organ. For example, the Cavitron ultrasonic aspirator, or CUSA, originally used for neurosurgery, enables physicians to cut across the liver while visualizing the blood vessels and bile ducts. The surgeon is then able to leave these structures intact and perform more precise resections. Using mechanical retractors and hemostatic tools has also helped to minimize the risk of surgery, explained Dr. Kinkhabwala.

New techniques for controlling blood flow in the liver, protecting the liver when deprived of oxygen, biochemical treatments to prevent liver injury, and management of the ischemic liver have also helped improve liver transplantation. Anesthesiologists are also specializing in the liver and are trained to manage the patient during liver resection, decreasing morbidity and improving recovery with more complicated surgeries. While common today, liver resections were not routinely performed until the 1980s, noted Dr. Kinkhabwala.

In the past, cutting the organ and

removing parts of the liver associated with disease often resulted in complications such as bleeding and liver failure, which could prove fatal. "This had to do with a poor understanding of the liver anatomy, liver disease, and lack of access to technological tools," said Dr. Kinkhabwala. Improved knowledge of liver anatomy also has helped surgeons understand how to perform living donor transplants, in which only a portion of the liver is removed from an individual and transplanted into a patient, noted Dr. Emond. Physicians are now extending such anatomic knowl-

edge and surgical techniques to patients with cirrhosis, according to Dr. Kinkhabwala. These individuals have scar tissue in their liver, which presents unique challenges to surgeons.

"Hepatic resection used to be contraindicated because of bleeding and liver failure," he said. "Now, physicians are able to perform surgery on selected patients, resulting in good outcomes."

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had been in the tail of the pancreas, he explained, it might have been possible to remove a portion of the organ and leave other parts of the GI tract intact.

But "the head of the pancreas and the duodenum have a shared blood supply," Dr. Lieberman said, "so it's not possible to take one organ and not the other. The bile duct also runs through the substance of the head of the pancreas, so that necessitates removing a portion of the bile duct and reconstructing it as well."

Patients undergoing a Whipple procedure often require 2 to 3 months of recovery before GI function returns to normal. But the patient in this case "just flew through the operation," Dr. Pochapin said.

In general, patient outcomes during and after Whipple procedures have greatly improved in recent years. "In the '80s, the perioperative mortality rate was as high as 25% for patients undergoing pancreaticoduodenectomy with the Whipple procedure," said Dr. Lieberman. "Now, however, in experienced centers such as ours, the rates are 3% or less." This is remarkable considering the advanced age of many patients undergoing a Whipple procedure, some of whom are even in their 90s. And, because of excellent supportive care, postoperative morbidity has also become less of an issue, he said.

Dr. Lieberman added that the patient in this case was a "prime example" of how, in the modern era, a patient can undergo a complicated surgical procedure with a relatively low risk of perioperative mortality and long-term side effects and resume a normal lifestyle afterward. The operation, he added, "eliminated the possibility that she would have developed a full-fledged pancreatic cancer with a very poor outcome in the future."

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