New Evolution® Biliary Eases Stent Placement

“The process of placing a metal stent is much more difficult than a plastic biliary stent. As a fellow, every opportunity to place a metal biliary stent is very important. The plastic stent does not expand or need to be deployed, so essentially you place the stent where it needs to be and the process is complete. Since the metal stent is expanding, it needs to be deployed in the correct position and that position needs to be held during deployment.

“The Evolution stent makes this process easier as it is controlled in its release and you can adjust during deployment. There is a clear point of no return in the deployment process. The markings are very clear and the deployment process is much easier given the control you have over the stent.”

— Nilay Kavathia, MD

Restoring Biliary Flow with the Evolution Metal Stent

Brenda Dennert, MD, and GI Fellow Nilay Kavathia, MD, share their clinical case experience with the new Evolution Controlled-Release Biliary Uncovered Stent.

Indications

The patient is 59 years old with metastatic pancreatic adenocarcinoma, which was recently diagnosed. The patient was seen by Oncology and was planned for palliative chemotherapy. The patient was told that the chemotherapy would only be administered if his bilirubin were less than 3.0 mg/dl. The patient’s pancreatic cancer was causing biliary obstruction with a bilirubin level of 7.2 gm/dl with debilitating pruritus.

Devices and Accessories

For the ERCP, a standard sphincterotome with a .035” Acrobat Calibrated Tip Wire Guide was used to cannulate the common bile duct. An Evolution Biliary Controlled-Release uncovered stent that was 8 cm was placed into the common bile duct.

Presentation and Diagnosis

The patient was otherwise healthy until admission to the hospital after his family noticed the patient was “turning yellow.” The patient reported a 20-pound weight loss and some fatigue but otherwise felt well. Initial lab work showed a significantly elevated bilirubin at 8.6 gm/dl and transaminases consistent with biliary obstruction. A CT scan showed a 2.7 x 2.9 x 3.0 cm lesion in the head of the pancreas suspicious for pancreatic malignancy. There were also metastatic lesions seen in the liver. As the work up continued, the patient was noted to have a significantly elevated CA19-9 at 2156. A biopsy of the liver lesion confirmed that this was stage IV pancreatic adenocarcinoma.

Given the metastatic nature of the cancer, surgical options were not present. The patient was seen by Oncology for palliative chemotherapy. The oncology team stated the patient was a candidate for palliative chemotherapy as long as bilirubin remained less than 3 gm/dl. The patient was presented options of percutaneous biliary drain or endoscopic stenting of the common bile duct. It was unlikely that a plastic biliary stent would be adequate as it would likely migrate or clog. The patient was scheduled for an uncovered metal stent.

New Evolution Biliary, continued on page 7

See Dr. Mankanwal Singh Sachdev’s Evolution Biliary case on page 3
Mayo Clinic Study Finds Endoscopic Option as Effective as Esophagectomy in Early Esophageal Cancer

Michael B. Wallace M.D., MPH
Professor of Medicine
Mayo Clinic in Florida

Use of a minimally invasive endoscopic procedure to remove superficial, early stage esophageal cancer is as effective as surgical intervention, according to a study by researchers at Mayo Clinic in Florida. The research, published in *Clinical Gastroenterology and Hepatology*, examined national outcomes from endoscopic resection treatment compared to esophagectomy.

“Our study on national outcomes, as well as our own experience with the procedure at Mayo Clinic in Florida, suggests that both procedures offer similar chances for cure and long-term survival,” according to Michael B. Wallace, MD, a gastroenterologist at Mayo Clinic in Florida. “Patients now have the option to preserve their esophagus when only early stage cancer is present.”

Study researchers examined national outcomes from the two procedures in patients with esophageal adenocarcinoma, the most common type of esophageal cancer in the US. The research team examined data from the National Cancer Institute’s Surveillance, Epidemiology and End Results (SEER) database.

They identified 1,619 patients with superficial, early stage esophageal adenocarcinoma who had endoscopic therapy (19 percent) or surgery (81 percent) from 1998 through 2009. Many of these patients were treated for cancers that arose from Barrett’s esophagus, a condition in which the cells in the lower part of the esophagus morph into a precancerous state.

The researchers collected survival data through the end of 2009, and found that endoscopy therapy increased progressively – from 3 percent in 1998 to 29 percent in 2009 – and was more often used in older patients. After adjusting for patient and tumor factors, the researchers concluded that patients treated by endoscopy had similar overall survival times compared to surgery.

“Endoscopy therapy for early stage esophageal cancer is becoming an acceptable method for all patients with very early esophageal cancer,” Dr. Wallace said. He adds that because of its complexity the procedure is generally offered at centers that have extensive experience in a multidisciplinary approach to endoscopic therapy.

Dr. Wallace hopes that this and other studies will encourage at-risk patients to get screened and follow up with their physicians. “We hope that patients and their physicians will continue to comply with follow up for Barrett’s esophagus,” he said. “This treatment option is limited to patients with very early cancer and high-grade dysplasia (pre-cancerous), so it is very important to follow surveillance schedules to catch the disease early. Later-stage cancer will still require surgery, often with chemotherapy and radiation.”

As to expanding the adoption of EMR in practice, Dr. Wallace feels that training is key. “There are a number of training options through centers of excellence, such as Mayo Clinic, and there are now such centers in virtually every region of the US. As with all complex procedures, the outcomes are best if done in centers with high volume and all the necessary technologies.”

Co-authors of the study include Mayo Clinic gastroenterologists Saowanee Ngamruengphong, MD, and Herbert Wolfsen, MD.

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New Evolution Biliary, continued from page 1

**Procedure**

The patient was given prophylactic antibiotics and brought to the endoscopy suite. The procedure was performed under general anesthesia. Using standard ERCP technique, the endoscope was positioned near the ampulla, which was normal appearing without any bile flow noted. The common bile duct was cannulated with a standard sphincterotome and a .035” Acrobat Calibrated Tip Wire Guide. This wire was chosen as the bile duct was significantly decompressed and accessing the proximal duct would likely be difficult. Once the wire was seen advancing into the intrahepatic ducts, a cholangiogram was obtained. The cholangiogram showed a significantly dilated proximal CBD at 18 mm without contrast seen in the distal 5 cm. A small sphincterotomy was performed without any bile flow noted.

An 8 cm Evolution Controlled-Release uncovered biliary stent was advanced into the common bile duct over the wire guide. The stent was positioned to traverse the stricture and slowly deployed using the controlled-release mechanism. Under fluoroscopic guidance the stent was re-positioned to an optimal position and then deployed. There was a significant gush of dark bile and biliary debris and stones.

**Outcome**

The procedure was technically successful as biliary flow was restored. There was an immediate response in terms of serum bilirubin and symptomatic pruritus. The patient was able to start palliative chemotherapy and on most recent labs 4 months post procedure the bilirubin remains normal. The patient was very satisfied with the procedure.