Treating gastroduodenal outlet obstruction

with the Evolution Duodenal Controlled-Release Stent

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A 73-year-old patient was referred to us with a "painless" obstructive jaundice and pruritus secondary to a solid lesion of the pancreas. The patient was admitted to our unit with MRI and CT-scan imaging of a solid lesion of the head of the pancreas with signs of vascular involvement of mesenteric vessels and bile duct obstruction and no certain metastasis. The patient's underlying diseases were diabetes and hypertension. A blood test showed AST 168 U/L, ALT 79 U/L, γ-GT 1066 U/L, ALP 650 U/L, total bilirubin 21.52 mg/dL, and dir. Bil. 14.54 mg/dL.

Under deep sedation with propofol, the patient underwent ERCP that failed for a tight stricture of the second part of the duodenum (Figures 1-A, 1-B). During the procedure we decided to place a duodenal 6 cm Evolution stent (Cook Medical EVO-22-27-6-D) after a measurement of the length of stenosis with the guide catheter (Cook Medical SIS-10). The deployment of the Evolution stent under fluoroscopy was comfortable as usual (Figures 2-A, 2-B).

After two days an ERCP was technically unsuccessful as the papilla was inaccessible despite probing within the duodenal stent. Thus, EUS-guided puncture was performed transgastrically into the left intrahepatic ducts. A linear array echoendoscope was placed near the gastric lesser curve allowing visualization of a dilated left hepatic duct (Figures 3-A, 3-B).

Upon confirming a tight stricture of the distal part of the common bile duct, we passed a wire guide, under fluoroscopy, into the biliary tree and towards the stricture as far as the third part of the duodenum. Fistula creation was necessary to allow the insertion of a SEMS. We placed an anterograde biliary stent (Cook ZILBS-635-10-6) across the stricture in a transpapillary position (Figures 4-A, 4-B).

An immediate good bile and contrast efflux was seen. The patient continues to show no signs or symptoms of gastric outlet obstruction or stent dysfunction. He is currently free of pruritus and undergoing palliative care.

Figure 1-A

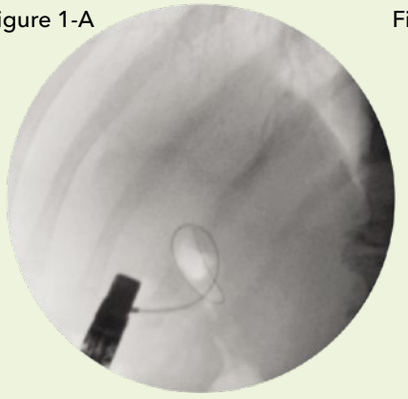


Figure 1-B

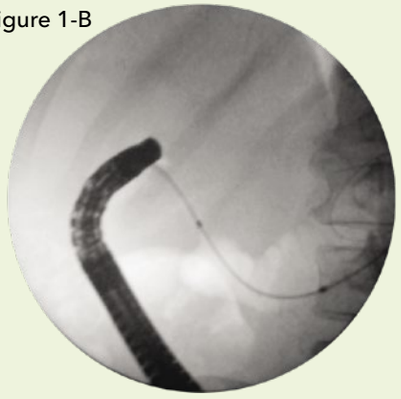


Figure 2-A

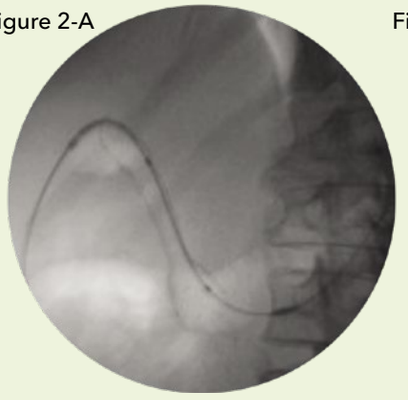


Figure 2-B

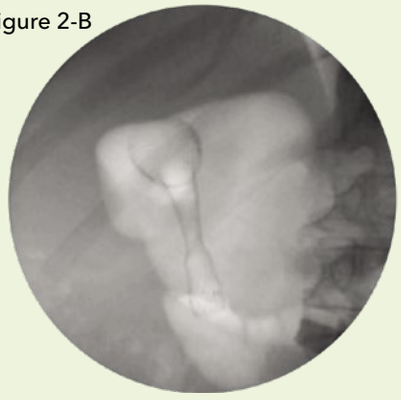


Figure 3-A

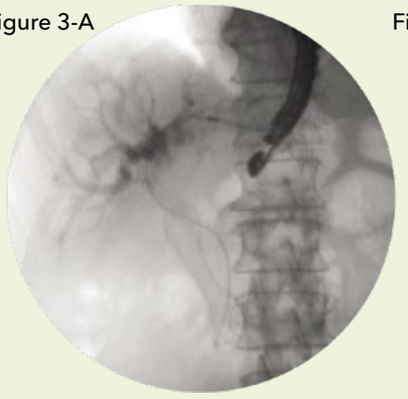


Figure 3-B

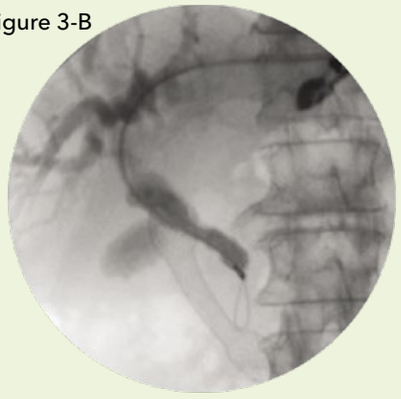


Figure 4-A

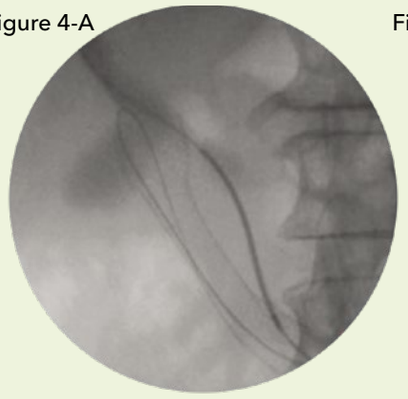
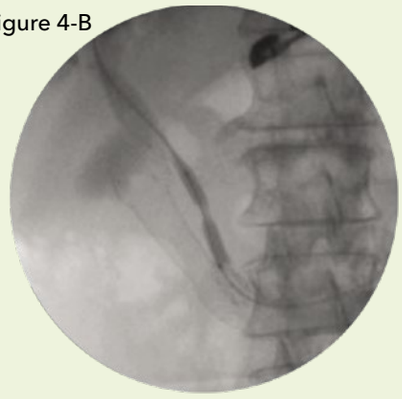


Figure 4-B



Evolution® Duodenal Stent System – Uncovered

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

INTENDED USE: This device is used for palliative treatment of duodenal or gastric outlet obstruction and duodenal strictures caused by malignant neoplasms.

CONTRAINDICATIONS: Those specific to GI endoscopy and any procedure to be performed in conjunction with stent placement. • Additional contraindications include, but are not limited to: enteral ischemia, suspected or impending perforation, intra-abdominal abscess/perforation, inability to pass wire guide or stent through obstructed area, patients for whom endoscopic procedures are contraindicated, coagulopathy/patients with elevated bleeding times, benign disease.

WARNINGS: The stent is not intended to be removed or repositioned after stent placement and is intended to remain in the body permanently. Attempts to remove or reposition stent after placement may cause damage to surrounding tissue or mucosa. • Stent cannot be retrieved after the deployment threshold has been passed. Corresponding marks on outer catheter and delivery handle indicate when threshold has been passed. • The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

PRECAUTIONS: Refer to product package label for the minimum channel size required for this device. • A complete diagnostic evaluation must be performed prior to use to determine proper stent size. • If wire guide or stent cannot advance through obstructed area, do not attempt to place stent. • Stent should be placed using fluoroscopic monitoring with endoscopy. • The stent should only be placed with the Cook delivery system, which is provided with each stent. • This device is intended for palliative treatment only. Alternate methods of therapy should be investigated prior to placement. • After stent placement, alternative methods of treatment such as chemotherapy and radiation should not be administered as this may increase risk of stent migration due to tumor shrinkage, stent erosion, and/or mucosal bleeding. • Long-term patency of this device has not been established. Periodic evaluation is advised.

POTENTIAL COMPLICATIONS: Those associated with GI endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, reflux, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest. • Additional complications include, but are not limited to: pancreatitis, intestinal perforation, pain, inadequate expansion, stent misplacement and/or migration, tumor ingrowth or overgrowth, stent occlusion, ulcerations, pressure necrosis, erosion of the luminal mucosa, septicemia, foreign body sensation, bowel impaction, death (other than due to normal disease progression).

See Instructions for Use for full product information.

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