Results from case studies are not predictive of results in other cases. Results in other cases may vary.

CAUTION: The law, including federal (USA) law, restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

NOTE: Use of the WallFlex Biliary RX Fully Covered Stent for the treatment of benign strictures or stenoses has not been cleared for use in the United States.

WARNING: The safety and effectiveness of the WallFlex Biliary RX Stent for use in the vascular system has not been established.

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PATIENT HISTORY

A 76-year-old man presented with abdominal distention and jaundice, with a bilirubin reading of 312 mmol/L, and CA19-9 of more than 1000. A CT scan showed a soft tissue shadow on the head of the pancreas with an enlarged bile duct. An MRCP showed a stenosis on the lower part of bile duct with enlarged intra- and extra-hepatic ducts. A diagnosis of carcinoma at the head of the pancreas and bile duct obstruction was confirmed. The patient refused surgery, and drainage of the bile duct was selected to relieve the obstruction.

PROCEDURE

An Autotome™ RX Sphincterotome was deployed through the duodenoscope and inserted into the bile duct under the guidance of a Hydra Jagwire® Guidewire. The radiography image showed that there was a stricture at the lower part of the bile duct, which was about 4cm in length. Following an exchange, an 10mm x 80mm fully covered WallFlex Biliary RX Stent was inserted into the common bile duct. Post placement, a large quantity of bile poured into the intestine. The stent expanded very well after deployment, with excellent visibility under X-ray and good tissue compliance.

TECHNOLOGY UPDATE

In my opinion, metal stents are the most effective method for the treatment of a malignant stenosis in the common bile duct where surgery is not an option. They may decrease the frequency of reintervention, reduce medical costs, and increase the survival rate of patients. The WallFlex Biliary RX Stent is designed for rapid exchange, and it is easy to use. The platinum core and the Nitinol outer skin provide the extremely strong contrast visibility for the stent, and the enhanced ratio of overall length versus radiopacity increases the handleability of surgery.

The radial expansionary force makes the stent resist crumpling in case of restenosis. The excellent flexibility of the stent may be helpful when it is deployed in tortuous anatomy, which may also maintain the clearance and physiological compliance of the inner space of the stent. The closed loop design on both ends of the stent decreases the potential for injury to the surrounding tissue. The flared design of the stent allows it to be easily observed and accurately placed. In summary, the WallFlex Biliary RX Stent is easy to deliver, deploys rapidly, and complies with the anatomy, which is a good choice for the treatment of a malignant stenosis in the bile duct.

Case presented by:
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