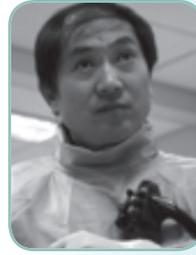


Benign Biliary Strictures Managed With the WallFlex™ Biliary RX Fully Covered Stent System RMV



CASE PRESENTED BY:

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PATIENT HISTORY

A 73-year-old male was admitted with a chief complaint of jaundice for approximately ten days. He had a long history of alcohol intake. An abdominal CT scan revealed a dilated common bile duct, an enlarged pancreatic head and a granular calcification in the pancreas.

PROCEDURE AND PATIENT OUTCOME

Upon examination he was jaundiced, underweight and malnourished. Laboratory investigations revealed obstructive jaundice. The tumor marker was normal. An endoscopic retrograde cholangiopancreatography (ERCP) revealed a mid-common bile duct stricture with proximal duct dilatation (Figures 1-4). A 6cm WallFlex Biliary RX Fully Covered Metal Stent was placed. Cytology brush examination was negative. After seven months, a final ERCP revealed complete resolution of the stricture and the stents were removed (Figures 5-8).

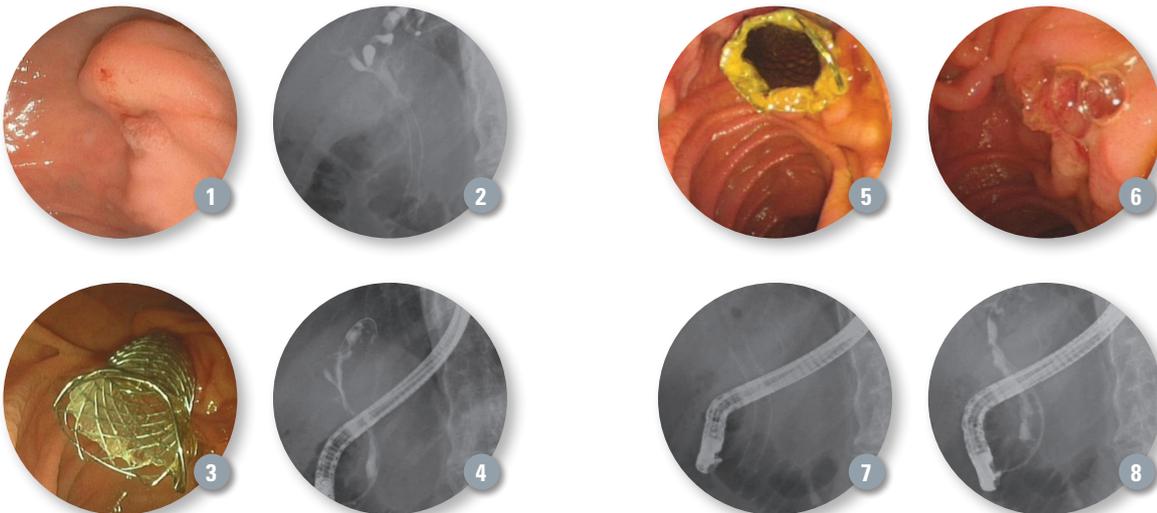
DISCUSSION

From 2010 to 2011, WallFlex Biliary RX Fully Covered Metal Stents were placed in 36 patients with benign biliary strictures in our hospital. When adequate biliary drainage was achieved, metal stents were removed. Resolution of the benign biliary strictures was found in 28 of 36 patients (77.8%). All fully covered metal stents were removed successfully. Placement of fully covered metal stents for benign biliary strictures is safe and effective.

Results from our experience are summarized in **Table 1**.

Table 1: Fully covered metal stent for treatment of benign biliary strictures

Number of patients	36
Sex (male / female)	17 / 19
Median age (y)	55.4
Etiology of BBS	
• Chronic pancreatitis	16
• Biliary calculi	12
• Surgical	8
CSEMS length	
• 6cm	23
• 8cm	13
Early complication	
• Mild acute pancreatitis	3
Late complication	
• Stent migration	1
Median stent placement time	2.4 months
Removal rate of stent	36 / 36
Immediate resolution rate of stricture	28 / 36



NOTE: The WallFlex Biliary RX Fully Covered Stent System RMV is CE marked and available in regions outside of the US with indications for use in the palliative treatment of biliary strictures produced by malignant neoplasms, relief of malignant biliary obstruction prior to surgery and for use in the treatment of benign biliary strictures. In the US the device is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms, relief of malignant biliary obstruction prior to surgery and for indwell up to 12 months in the treatment of benign biliary strictures secondary to chronic pancreatitis.

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

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

CAUTION: The 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 labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

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ENDO-101308-AB December 2016