A Multi-Center, Prospective Study of the Wall Flex ® RX Biliary Fully Covered Stent for the Treatment of Benign Biliary strictures

Published: 28-01-2010
Last updated: 04-05-2024

Primary Objective: To assess the safety and performance of temporary placement of the Wall Flex Biliary RX as a Fully Covered Stent Treatment of Biliary obstruction that result from benign bile duct strictures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON32497

Source
ToetsingOnline

Brief title
The Wall Flex FC Benign Biliary stricture Study

Condition

- Gastrointestinal stenosis and obstruction
- Endocrine neoplasms benign

Synonym
benign blockage of the bile duct or benign biliary obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific
Source(s) of monetary or material Support: Sponsor: Boston Scientific Corporation

Intervention

Keyword: - Benign Biliary strictures, - Biliary stenting

Outcome measures

Primary outcome

Primary Endpoint: Stent Removability, defined as ability to remove the stent endoscopically without stent removal related serious adverse events as Assessed from the time of stent removal to 1 month post-stent removal.

Secondary outcome

Secondary Endpoints:

1. Stricture during stent indwelling resolution, defined by lack of stent-related re-interventions
2. Stricture resolution after stent removal, defined by lack of stricture-related re-intervention
3. Occurrence and severity of adverse events related to the stent and / or the procedure
4. Ability to deploy the stent in satisfactory position across the stricture (technical success at placement)
5. Length of stent placement procedure, length of stent removal procedure and methods of removal (to include video recording if available)
6. Biliary obstructive symptom assessment at all visits
7. Liver Function Tests (LFTs) at baseline, at 1 month post-stent placement,

at stent removal and at 6 months, 12 and 24 post-stent removal

Study description

Background summary

This study will Assess the safety and performance of temporary placement of the Wall Flex ® Biliary RX as a Fully Covered Stent Treatment of Biliary obstruction that result from benign bile duct strictures.

Obstruction of the bile duct may be caused by benign or malignant Biliary strictures. Benign strictures may result from pancreatic disease, postoperative complications, sclerosing cholangitis and a variety of rarer causes.

Benign and malignant Biliary strictures are commonly managed endoscopically by endoscopic retrograde cholangiopancreatography (ERCP) with or without balloon Dilation, sphincterotomy, and stent placement.

Stents may be placed endoscopically in patients with malignant or benign Obstructions for long-term palliation or as temporary therapy. Plastic stents have been used for treatment of post-liver transplantation and cholecystectomy bile leaks, bile duct stones, and benign bile duct strictures. It is anticipated that these stents will occlude over time, and most physicians will exchange the stent as needed, or will routinely exchange them at 3-month intervals.

Benign Biliary strictures may be diagnosed with computed tomography (CT) and ultrasound, however, endoscopic ultrasound (EUS) and ERCP have become the more reliable diagnostic tools. Limited data are available comparing endoscopic and surgical treatments for benign Biliary strictures. Repeat surgery, however, is reported to have 10% mortality and 10% -30% stricture recurrence rates6. Successful treatment of post-operative Biliary strictures (POBS) correlates to the time of diagnosis following injury, and therapy may include surgery, percutaneous transhepatic and endoscopic techniques.

Endoscopic treatment using temporary placement of plastic stents provides a proven therapeutic alternative for Biliary obstruction secondary to benign bile duct strictures. In this minimally invasive approach, the bile duct stricture is calibrated by successive placement of plastic stents, increasing, where possible, the number of stents at each stent exchange over several months to the goal of a stent-free product. This requires numerous ERCP procedures, typically three or more over numerous months. In general, the treatment goals are improvement in cholestasis, long-term absence of symptoms and Eradication of the stricture9.

- Post Operative Biliary strictures: Injury Associated With Biliary surgery

may result in leakage of bile from minor or major bile ducts, bile duct stenosis with or without leakage, or transection of the bile duct10. Management of post-operative Biliary strictures includes surgery with Roux-en-Y hepaticojejunostomy and / or treatment with percutaneous transhepatic dilatation and percutaneous drain placement. However, surgery is associated with morbidity, including a 10% -30% stricture recurrence rate11. Endoscopic treatment is becoming the first approach to treatment and is more likely to be successful if commenced early after the time of injury5, 6,8,10,12. According to Bergman et AL10 goal of the initial endoscopic treatment is to remodel the bile duct.

• Liver Transplantation: Complications from liver transplant may include Biliary leaks, anastomotic strictures and associated cholangitis5. Surgery is often the primary treatment method but carries significant risk and the need for retransplantation. Many of these patients experience or intrahepatic strictures that are recurring, which make surgery more difficult and less effective13.

• Chronic Pancreatitis: Incidence of strictures that result from chronic pancreatitis is reported between 3% -23% 15. Studies reviewed by Eickoff et al16 indicate that strictures caused by chronic pancreatitis may result in cholestasis, cholangitis, and Jaundice. Surgical drainage and endscopic therapy including stenting are the most common treatment methods. Vitale et al17 reported 80% success of stenting for chronic pancreatitis stenting with an average period of 13 months. Eickoff et al18 reported 46% of stricture regression and clinical improvement after a median stenting period of 9 months.

The placement of self-expanding metal stents (SEMS) in the bile duct for benign disease is becoming more common. Although literature does not document results of Removability metal stent in a prospective, controlled clinical trial, the presence of case reports and retrospective analysis of literature demonstrates that Removability metal stent is feasible. A review of 20 clinical study publications documents 310 metal stent removal attempts, 232 of which were from benign strictures. Duration of indwelling stent ranged from 0-28 months with stent removal reported as feasible in 90% of the cases. Severe complications reported include painful extraction, bile leak, bleeding, pain and ERCP-related pancreatitis.

Study objective

Primary Objective: To assess the safety and performance of temporary placement of the Wall Flex Biliary RX as a Fully Covered Stent Treatment of Biliary obstruction that result from benign bile duct strictures.

Study design

The study is designed as a multi-center, prospective, non-randomized study. Ten to 15 sites will participate, and enrollment of 187 patients is planned. The

proposed duration of the study is approximately 7 years 12 months for allo wing enrollment / treatment plus 6 years to complete follow-up. Patients will be followed for 5 years after stent removal.

Intervention

Patients who are consented and meet inclusion / exclusion criteria will undergo a stenting procedure with the Wall Flex Fully Covered Biliary RX Stent System.
The stent will remain in patients from the post-liver transplant cohort for 5 months (plus / minus 1 month) at which point it will be removed. The stent will remain in the form chronic pancreatitis patients and post-abdominal surgery cohorts for 11 months (plus / minus 1 months) at which point it will be removed.

Study burden and risks

Potential Complication Associated with Metal Stent Placement
- o Pain
- o Bleeding
- o Fever
- o Nausea
- o Vomiting
- o Infection
- o Inflammation
- o Recurrent Obstructive Jaundice
- o Stent occlusion
- o Stent fracture
- o Mucosal hyperplasia
- o cholangitis
- o Cholecystitis *
- o Pancreatitis
- o ulceration and perforation of duodenal or bile duct
- o Stent migration
- o Death
- o Stent misplacement
- o Perforation of the gallbladder due to the stent covering the cystic duct *

* Note: In a small clinical trial of this device, two out of four (50%) subjects who had a stent placed across the cystic duct developed cholecystitis. One of these subjects Suffered a perforated gallbladder due to the stent covering the cystic duct, requiring a drain to be placed.
- o Hepatic abscess
- o Retransplant

Potential Complications Associated with Stent Removal (additional to those listed above)
- o Abscess with fistula formation

o Wire mesh disruption
o Duodenal edema
o Stent wall embedment in CBD
o Bile leak

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age 18 or older
• Willing and able to comply with the study procedures and provide written informed consent to participate in the study
• Chronic pancreatitis or prior liver transplantation or other prior abdominal surgery (cholecystectomy to include)
• Indicated for ERCP with stent placement procedure for:

o Symptomatic bile duct stricture (ie obstructive Jaundice, persistent cholestasis, acute cholangitis) confirmed by cholangiogram and / or
o Bile duct stricture confirmed by cholangiogram and / or
o Exchange of prior plastic stent (s) for management of benign stricture

Exclusion criteria

General
• Placement of the stent in strictures that can not be dilated enough to pass the delivery system
• Placement of the stent in a perforated duct
• Placement of the stent in very small intrahepatic ducts
• Patients for whom endoscopic techniques are contraindicated
• Biliary stricture of malignant etiology
• Biliary stricture or benign etiology other than chronic pancreatitis or liver transplant anastomosis or other abdominal surgery
• duct stricture within 2 cm of Bifurcation
• Symptomatic duodenal stenosis (with gastric stasis)
• Prior Biliary self-expanding metal stent
• Suspected stricture ischemia based on imaging of hepatic artery occlusion or endoscopic evidence of Biliary cast syndrome
• Known bile duct fistula
• Known sensitivity to any components of the stent or delivery system
• Participation in another investigational study within 90 days prior to or during the study consent ;Additional Specific to Chronic Pancreatitis Patients
• Developing Biliary obstructive symptoms associated with an attack of acute pancreatitis ;Additional Specific to Post-Abdominal Surgery Patients
• History of hepatectomy
• History of liver transplant (only for post-abdominal surgery group);Additional Specific to Liver Transplant Patients
• Live donor transplantation

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2010
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Wall Flex ® RX Biliary Fully Covered Stent
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	28-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30240.078.09