A fully covered self-expandable metal stent with antimigration features for benign biliary strictures: a prospective, multicenter cohort study CME

Daisy Walter, MD,[1] Wim Laleman, MD, PhD,[2] Jeroen M. Jansen, MD,[3] A.W.M. van Milligen de Wit, MD, PhD,[4] Bas L. Weusten, MD, PhD,[5] Petra G. van Boeckel, MD, PhD,[1] Meike M. Hirdes, MD, PhD,[1] Frank P. Vleggaar, MD, PhD,[1] Peter D. Siersema, MD, PhD[1]

Utrecht, Amsterdam, Breda, Nieuwegein, the Netherlands; Leuven, Belgium

Background: Self-expandable metal stents (SEMSs) are increasingly used for the treatment of benign biliary strictures (BBSs). A new fully covered SEMS (FCSEMS) with flared ends and high conformability was designed to prevent migration of the stent.

Objective: To evaluate the efficacy of a novel FCSEMS with antimigration features.

Design: Prospective cohort study.

Setting: Five hospitals in the Netherlands and Belgium.

Patients: Consecutive patients with BBS.

Intervention: FCSEMS placement for 3 months.

Main Outcome Measurements: Initial and long term clinical success, stent migration rate and safety.

Results: Thirty-eight patients (24 men; mean age, 53 ± 16 years) were included. Stent placement was technically successful in 37 patients (97%). Two patients died of an unrelated cause before stent removal, and no data on these patients were available on stricture resolution. Initial clinical success was achieved in 28 of 35 patients (80%). During follow-up after stent removal, a symptomatic recurrent stricture developed in 6 of 28 patients (21%). Overall, the long-term clinical success rate was 63% (22 of 35 patients). Stent migration occurred in 11 of 35 patients (31%), including 5 symptomatic (14%) and 6 asymptomatic (17%) migrations. In total, 11 serious adverse events occurred in 10 patients (29%), with cholangitis (n = 5) being most common.

Limitations: Nonrandomized study design.

Conclusions: Good initial clinical success was achieved after placement of this novel FCSEMS, but stricture recurrence was in the upper range compared with other FCSEMSs. The antimigration design could not prevent migration in a significant number of patients with a persisting stricture. (Gastrointest Endosc 2015;81:1197-203.)

Abbreviations: BBS, benign biliary stricture; FCSEMS, fully covered self-expandable metal stent; IQR, interquartile range; SAE, serious adverse event; SEMS, self-expandable metal stent.

DISCLOSURE: *The following author disclosed financial relationships relevant to this article: Dr Siersema is on the Advisory Board of Boston Scientific and has received research support from Cook Medical. All other authors disclosed no financial relationships relevant to this article.*

See CME section; p. 1237.

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2014.10.026

Received April 14, 2014. Accepted October 24, 2014.

Current affiliations: Gastroenterology and Hepatology, University Medical Center Utrecht, Utrecht, the Netherlands (1), Liver and Biliopancreatic Disorders, University Hospital Gasthuisberg, KU Leuven, (2), Gastroenterology and Hepatology, Onze Lieve Vrouwe Gasthuis, Amsterdam (3), Gastroenterology and Hepatology, Amphia Hospital, Breda (4), Gastroenterology and Hepatology, St. Antonius Hospital, Nieuwegein (5), the Netherlands.

Reprint requests: Daisy Walter, MD, Department of Gastroenterology and Hepatology, University Medical Center Utrecht. P.O. Box 85500, 3508 GA Utrecht; the Netherlands.

If you would like to chat with an author of this article, you may contact Dr Walter at d.walter@umcutrecht.nl.

Benign biliary strictures (BBSs) may develop as a result of a variety of causes, of which chronic pancreatitis and postsurgery bile duct injuries, either after cholecystectomy or at the anastomotic site after liver transplantation, are most frequently encountered.[1] To prevent the occurrence of serious adverse events (SAEs) caused by these strictures, including jaundice, cholangitis, and secondary biliary cirrhosis, biliary decompression is recommended.[2]

Endoscopic therapy with the placement of multiple plastic stents has evolved as the first-choice treatment modality for biliary dilation. Treatment consists of sequential stenting with increasing numbers of plastic stents during a 1-year period with 3-month stent exchanges to preclude stent obstruction. With this approach, stricture resolution is achieved in 80% to 89% of patients with postsurgery strictures[3-6] and in 31% to 92% of patients with chronic pancreatitis.[4,5,7,8]

A major drawback of this therapy is the need for frequent stent exchanges to prevent or manage stent occlusion, even if multiple stents are placed.[8,9] In an attempt to improve stent patency and reduce the number of procedures required, self-expandable metal stents (SEMSs) have been introduced as an alternative for plastic stents because of their larger luminal diameter. It has already been demonstrated that SEMSs have a longer stent patency compared with that of plastic stents in patients with malignant biliary strictures.[10] Uncovered SEMSs for benign strictures are not desirable because of tissue ingrowth through the stent mesh resulting in a limited long-term stent patency and difficulties with removal over time.[11-15] Therefore, fully covered SEMSs (FCSEMSs) are increasingly preferred to treat benign strictures.

The advantage of FCSEMSs is the possibility of easy stent removal in case of adequate dilation of the stricture or in case of stent dysfunction. However, as embedding of the stent mesh in the mucosa is unlikely to occur, stent migration is a frequently encountered problem with migration rates as high as 41%.[16-21] To prevent migration, several antimigration features have been tested with varying results, including stents with antimigration fins,[19,20] double-pigtail stents for anchoring,[22] and stents with flared ends.[19,23]

Moon et al[23] recently reported excellent results for the prevention of migration by using the Niti-S bumpy type stent (Taewoong Medical, Seoul, South Korea) in patients with benign pancreatic duct strictures. The Niti-S bumpy type stent is fully covered and has 2 antimigration features, including a high conformability at the middle part of the stent and flared stent ends at both sides. Until now, no data have been available on the use of this stent for strictures in the biliary tract. Therefore, the aim of our study was to prospectively assess the efficacy of this FCSEMS with antimigration features in patients with BBSs.

PATIENTS AND METHODS

Patients

Between August 2010 and April 2013, consecutive patients with BBSs were enrolled in this prospective, multicenter study at 2 tertiary referral hospitals and 3 general hospitals in the Netherlands and Belgium. Inclusion criteria for enrollment were (1) clinical symptoms of biliary obstruction and/or an extrahepatic biliary stricture seen during ERCP, (2) a benign etiology of the extrahepatic bile duct stricture, as confirmed by a CT scan and/or EUS, (3) age 18 years or older, and (4) stent placement feasible during ERCP. Exclusion criteria were (1) a peripheral or hilar biliary stricture, (2) a stricture caused by primary sclerosing cholangitis, (3) previous metal stent placement, and (4) a history of surgical hepaticojejunostomy, choledochojejunostomy, or choledochoduodenostomy. Patients with previously failed plastic stent placement, defined as a persistent stricture after plastic stent removal, could be included in the study. All patients provided written informed consent. The study was approved by the medical ethics committee of all participating centers and registered at the Dutch Trial Register (NTR 1910).

Niti-S biliary bumpy stent

The Niti-S biliary bumpy stent (Taewoong Medical) is a SEMS constructed of nitinol wire with bilateral flared ends (Fig. 1). The flared ends are covered with silicone, whereas the body of the stent is covered with a polytetrafluoroethylene membrane. At the body of the stent, the cell sizes are irregular, resulting in different segmental radial forces and a high conformability. The combination of the high conformability and the flared ends are proposed to reduce the risk of stent migration. A removal string is attached on the proximal stent end. The stent is available in 4-, 6-, 8-, 10-, and 12-cm lengths. For this study, stents with a diameter of 10 mm were used.

Stent placement and removal

Stent placement was performed during ERCP with patients under conscious sedation with midazolam or propofol, monitored anesthesia care, or general anesthesia. After biliary cannulation, stricture location and length were determined with fluoroscopy, and the appropriate stent length was determined. The stent was placed across the stricture with approximately 1 cm of the stent exposed to the duodenal lumen. Removal was performed with rat-tooth forceps by grasping the distal end of the stent after a 3-month dwell time. The effect of dilation on the biliary stricture was assessed by fluoroscopy immediately after stent removal. In case of a persisting stricture, a new stent (plastic or metal) was placed at the discretion of the treating physician.