

Title:

Insertion of fully covered self-expanding metal stents in benign biliary diseases

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Insertion of fully covered self-expanding metal stents in benign biliary diseases

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ABSTRACT

Introduction: Benign biliary diseases are traditionally treated using plastic stents. However, fully covered self-expanding metal stents are currently gaining acceptance for the treatment of these pathologies.

Objective: To assess the effectiveness and complications associated with the placement of temporary endoscopic fully covered self-expanding metal stents for the treatment of benign biliary diseases.

Materials and methods: This was a retrospective and observational study using a prospective database from a tertiary care center from March 2012 to May 2016. Some patients that had a fully covered metal stent due to a benign biliary disease were also included. The indications, resolution, technical success rates and adverse events were documented.

Results: 31 patients were included with a total of 34 stents inserted. The indications were as follows: 8 (25%) post cholecystectomy biliary stenoses, 11 (31%) large or multiple choledocholithiasis, 3 (8.3%) biliary fistulas, 2 (6%) post-liver transplant stenoses, 2 (8.3%) papillary stenoses, 2 (6%) perforations and 2 (6%) bleeds. The global resolution success rate of the stents for all pathologies was 88%, this included 87.5% (7/8) in post cholecystectomy stenoses, 73% (8/11) in large choledocholithiasis and 100% for the remaining indications. Thirty-three of 34 stents were removed after an average of 133 days (ranging from 10 to 180 days). No complications were registered.

Conclusion: Fully covered self-expanding metal stents are an effective and reliable alternative for the resolution of benign biliary diseases.

Key words: Metal stent. Benign biliary diseases. ERCP.

INTRODUCTION

Plastic biliary stents were first used in 1980 (1) and the use of self-expanding metal stents began at the end of the same decade (2,3). Initially, both types of stents were used to treat malignant biliopancreatic pathologies and were later used to treat benign ductal obstructions.

Benign biliary stenosis that mainly occurs post-surgery was the first non-tumor stenotic indication for the use of biliary stents, initially via the insertion of two or more plastic stents (4). At present, fully covered self-expanding metal stents (FCSEMS) are gaining acceptance for the treatment of these types of stenoses. Its greater expansion strength, radial diameter, permeability and the low number of procedures mean that the range of indications has increased (5,6). In this article, we evaluate the effectiveness and the complications associated with the use of temporary endoscopic FCSEMS for the treatment of benign biliary pathologies. These are classified as obstructive and non-obstructive (Fig. 1).

MATERIALS AND METHODS

This was a retrospective and observational study using a prospective database. The study was conducted in a tertiary care center from March 2012 to May 2016. Patients with a FCSEMS inserted due to a benign biliary disease were included.

The indications, technical success rates (placement and extraction of stents), resolution rates and complications were recorded. The WallFlex Biliary Rx Fully Covered FCSEMS was used which was 10mm in diameter x 60mm in length (Boston Scientific).

Definitions

- *Surgical bile duct injury (SBDI)*: obstruction (ligation, clipping and cicatricial stenosis) or total or partial section of the main bile duct or the aberrant ducts that drain a hepatic segment.
- *Complex choledocholithiasis*: multiple lithiasis (three or more, at least one of them larger than 20mm) and/or lithiasis larger than 20mm and/or lithiasis impacted in the bile duct.
- *Type II papillary stenosis*: narrowing of the bile duct at a papillary level, without compromising the distal common bile duct up to a length of 10 mm (inflammatory origin).
- *Refractory or high grade biliary fistulas*: continuity of the biliary tree that generates biliary discharge that occurs during ERCP, before the opacification of the intrahepatic biliary branches. These are refractory to the sphincterotomy or to the use of plastic stents.
- *Post sphincterotomy hemorrhage*: papillary bleeding following sphincterotomy, refractory to the standard endoscopic treatment (injection, thermal methods and/or hemoclips).
- *Bile duct perforation*: continuity in the bile duct wall in any area.
- *Post-transplant stenosis*: reduction of the bile duct caliber after a liver transplant.

Statistics

Statistical analysis was performed using a prospective computerized database in Excel. A descriptive evaluation with summary measures (percentage and range) of the data was performed using the SPSS 20.0 statistical package.

RESULTS

Thirty-one patients were included and the average age was 57 years old (27-90) and 66% were female (20). Thirty-four FCSEMS were inserted according to the following indications, 8 (25%) SBDI, 11 (31%) complex choledocholithiasis, 3 (8.3%) refractory or high grade biliary fistulas, 2 (6 %) post liver transplant stenoses, 3 (8.3%) type II papillary stenoses, 2 (6 %) iatrogenic biliary perforations and 2 (6%) post papillotomy refractory bleeds (Table 1). The insertion technical success rate was 100%. The resolution rate for the underlying pathology was 88%; 87.5% (7/8) in SBDI, 73% (8/11) in complex choledocholithiasis and 100% for the remaining indications. The average time from placement to extraction was 133 days (10-180 days) (Table 2). The use a second stent was necessary in 3 cases. There were 2 cases with SBDI and failure of the first treatment and 1 case of a resolved stenosis with the second stent and the other required surgical treatment. The third case was due to a post-transplant stenosis and was resolved with a second stent. The three patients with choledocholithiasis that did not respond to the FCSEMS were resolved via surgery.

Thirty-three of 34 FCSEMS were endoscopically extracted with no technical complications. The other stent was extracted during the pancreaticoduodenectomy procedure from a patient with resectable pancreatic cancer. The indication for the use of a FCSEMS in this case was a post sphincterotomy bleed refractory to the endoscopic therapeutic. No complications were registered during stent placement, stent extraction or due to stent migration.

DISCUSSION

FCSEMS seems to resolve the problem of prolonged biliary drainage for malignant biliary stenoses. Due to its greater permeability compared to plastic stents, this technique is

currently the first option for the treatment of extra hepatic malignant biliary stenoses. Furthermore, the indications for these stents also include benign biliary pathologies. It is important to note that the resolution rate for benign biliary pathologies using FCSEMS was 88% in this study, similar to that reported in the literature.

Many authors have emphasized the importance of plastic biliary stents in the treatment of complex choledocholithiasis, post-surgical stenoses and biliary fistulas. The mechanism of action is to ensure biliary permeability, to apply friction in the case of complex choledocholithiasis, to maintain a continued and progressive dilation in stenoses and to reduce the transpapillary pressure gradient in fistulas. With regard to benign stenoses, the resolution rates via multiple endoscopic sessions using a plastic stent are variable, between 40 and 90% according to different series (4,7). FCSEMS adds some special features that result in increased resolution rates of up to 91-92% (8,9).

In the case of complex choledocholithiasis, the greater radial expansions compress and grind the stones which ultimately lead to breakage, softening and a reduction in size (Fig. 2). Recent studies have also demonstrated that FCSEMS are an effective and reliable option for cases of a failed conventional extraction of lithiasis (6,10-14). In the context of stenoses, the FCSEMS creates a continued radial dilation that is equal to the action of three plastic stents, both at the papilla and the common bile duct from the initial ERCP (Fig. 3). The articles published in this area highlight a greater biliary clearance rate with a lower number of procedures. Thus, this technique is more cost-effective than the use of plastic stents (5,8,9). The study by Coté et al. (8) in 2016 is the only randomized and controlled study performed in this area. This study confirmed the hypothesis that metal stents are not inferior to plastic stents when used as an initial strategy and in fact resolve the stenosis in fewer sessions.

The study of Wang et al. (15) in 2009 that included 13 cases, recommended the insertion of FCSEMS in complex biliary fistulas, defined as those that do not respond to the initial endoscopic treatment with sphincterotomy and a plastic stent. The authors claim that the inserted stent can remain for up to sixteen months and there were no difficulties for the extraction. Our study showed a resolution of 100% without any migrations and the

average placement time was one hundred days. In the 2 cases of post sphincterotomy papillary bleeding, a FCSEMS was used due to the failure of the standard hemostasis techniques (injection and thermal and mechanical methods). This was due to the benefits that these stents provide such as a radial force of compression and a greater drainage diameter of the bile duct. The case reported by García-Cano and collaborators (16) in 2016 of a post sphincterotomy choledochal perforation responded to the insertion of a FCSEMS, which was withdrawn without difficulties two months later. As highlighted by the authors, bile duct perforations have excellent resolution rates when metal stents are used. The 2 cases reported here were resolved with the same treatment and no surgical intervention was required.

There were no significant complications during the placement and extraction of these stents. The percentage of reported distal migrations and papillary tissue hyperplasia without clinical consequences is low (5,6). This situation did not arise during any of the thirty four procedures reported here. However, one limitation of the study is the limited sample size and the retrospective design.

CONCLUSION

The FCSEMS are highly effective for the resolution of benign biliary pathologies and can therefore be considered as a reliable and effective alternative in some cases. The validation of this technique for the treatment of a benign biliary pathology requires randomized and cost-effective studies.

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Table 1. Indications for the insertion of fully covered self-expanding metal stents

<i>Indication</i>	<i>N° of patients</i>	<i>%</i>
Large or multiple lithiasis	11	35.4
SBDI	9	25.8
Biliary fistulas	3	9.6
Type II papillary stenosis	3	9.6
Post liver transplant stenosis	2	6.4
Perforation	2	6.4
Bleeding	2	6.4

SBDI: surgical bile duct injury.

Table 2. Average placement time of fully covered self-expanding metal stents

<i>Indication</i>	<i>Average time (days)</i>	<i>Range</i>
Complex choledocholithiasis	133	28-180
SBDI	144	42-180
Biliary fistulas	100	21-180
Type II papillary stenosis	134	42-180
Post liver transplant stenosis	180	180
Post papillotomy bleeding	10	10

SBDI: surgical bile duct injury.

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Table 3. Description of the analyzed cases

<i>Patient n°</i>	<i>Sex</i>	<i>Age</i>	<i>Indication</i>	<i>Technical success</i>	<i>Complications</i>	<i>Resolution</i>
1	F	45	SBDI	Yes	No	Yes
2	F	50	SBDI	Yes	No	Yes
3	F	56	SBDI	Yes	No	Yes
4	M	60	T II papillary stenosis	Yes	No	Yes
5	M	80	Large lithiasis	Yes	No	Yes
6	M	78	Large lithiasis	Yes	No	Yes
7	F	40	Post tx stenosis	Yes	No	Yes
8	M	79	Large lithiasis	Yes	No	Yes
9	F	45	SBDI	Yes	No	Yes
10	F	45	Post tx stenosis	Yes	No	Yes
11	M	80	Large lithiasis	Yes	No	Yes
12	M	80	T II papillary stenosis	Yes	No	Yes
13	F	45	SBDI	Yes	No	Yes
14	F	38	Biliary leakage	Yes	No	Yes
15	M	87	Large lithiasis	Yes	No	Yes
16	M	78	Large lithiasis	Yes	No	No
17	M	86	Post SPT bleeding	Yes	No	Yes
18	F	45	Large lithiasis	Yes	No	Yes
19	F	56	Biliary leakage	Yes	No	Yes
20	F	30	SBDI	Yes	No	No
21	F	33	SBDI	Yes	No	Yes
22	F	60	Large lithiasis	Yes	No	Yes
23	F	50	SBDI	Yes	No	Yes
24	F	27	Perforation	Yes	No	Yes

25	F	33	T II papillary stenosis	Yes	No	Yes
26	M	59	Perforation	Yes	No	Yes
27	F	40	Biliary leakage	Yes	No	Yes
28	F	89	Large lithiasis	Yes	No	Yes
29	F	80	Large lithiasis	Yes	No	No
30	M	69	Post SPT bleeding	Yes	No	Yes
31	F	90	Large lithiasis	Yes	No	No

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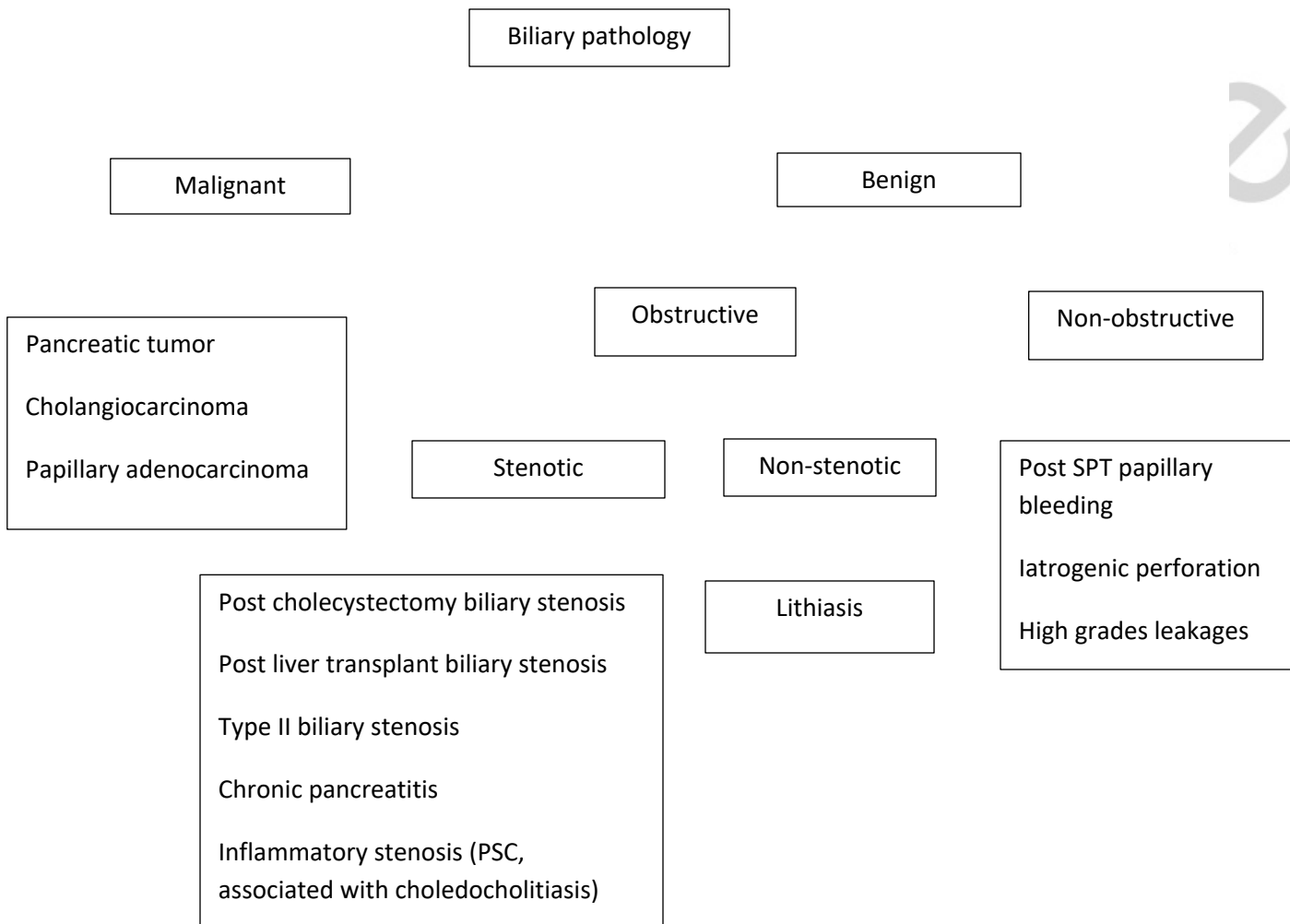


Fig. 1. Classification of biliary pathologies (SBDI: surgical bile duct injury. SPT: sphincter papillotomy. PSC: primary sclerosing cholangitis).

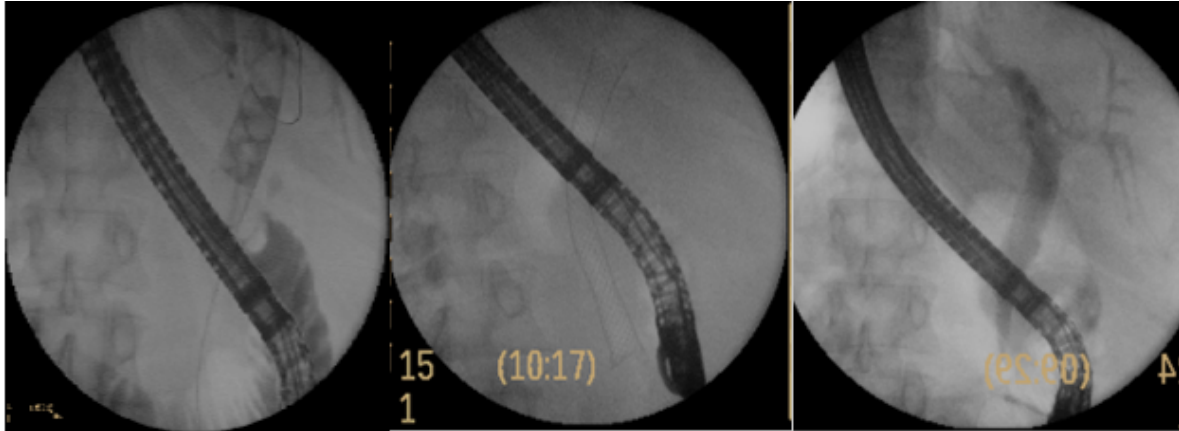


Fig. 2. Complex choledocholithiasis. Insertion of a fully covered self-expanding metal stent. ERCP following the extraction of the stent.

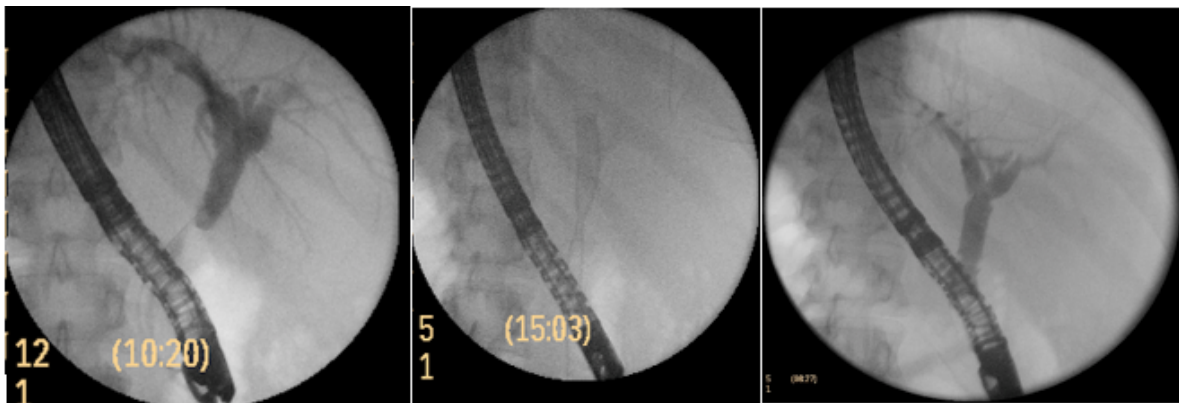


Fig. 3. Post laparoscopic cholecystectomy stenosis. Insertion of a fully covered self-expanding metal stent. Stenosis resolution.