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Research Article

Biliary Fully Covered Self-Expandable Metallic Stent Use in 149 Consecutive Patients

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Abstract

Objective: The main goal of the study is to show the indications of the fully covered self-expandable metallic stents used in our unit.

Method: Patients who underwent fully covered self-expandable metallic stents between January 1, 2018, and December 31, 2019, in our unit were included in the study. Endoscopic procedure reports were found by searching for "covered metallic stent" from the EndoCam operating system.

Result: There were a total of 149 patients in the study. The mean age of the patients was 57.44 ± 16.86 years. About 46.3% of the patients were women. Benign biliary stenosis in the common bile duct was the first with a rate of 36.2% in indications. Malignant biliary stenosis was in the second place at 11.4%, and post-transplant anastomotic stenosis was in the third place at 8.7%. The median time between insertion and removal sessions was 34 days (min: 5 days, max: 417 days) in patients (80%) whose fully covered self-expandable metallic stents were removed in our center.

Conclusion: Fully covered self-expandable metallic stents are used to treat a variety of benign and malignant biliary pathological conditions. However, fully covered self-expandable metallic stents may face stent migration issues that can be addressed with modifications.

Keywords: Endoscopy, endoscopic retrograde cholangiopancreatography, metallic stents

INTRODUCTION

Stent application in endoscopic retrograde cholangiopancreatography (ERCP) due to biliary stenosis was first applied in 1980 for malignant stenosis.[1] Toward the end of the same year, metallic stents began to be applied to benign strictures in ERCP.[2] In cases where metallic and plastic stents were applied, an improvement in the 30-day survival time and a decrease in morbidity rates were observed compared to surgical and percutaneous interventions.[3,4] With plastic stent occlusion and subsequent bacterial translocation, the incidence of cholangitis was high in these stents.[5] Therefore, plastic stents need to be removed and reinserted, leading to an increase in the number of procedures. Stent dysfunction seen in plastic stents can also be seen in metal stents. In these malignant disease applications, the spread of malignant tissue into the stent occurs through tissue hyperplasia due to chronic inflammation and biliary sludge.[6,7] However, the dysfunction of the metal stent compared to plastic stents was easily managed by mechanical cleaning or insertion of a separate metal stent into the stent.[8] Biliary metal stents are used in common bile duct stones, malignant biliary stenosis, benign biliary stenosis, bile leakage, and bleeding during ERCP. Metal stents have complications. One of the most common of these is tissue damage and bleeding caused by the destruction of the duodenal mucosa by the tip inside the duodenum. In addition, stent migration is a common complication of biliary stenting. With this study, our main goal is to show the indications of the fully covered self-expandable metallic stents (FCSEMS) used in our unit.

METHODS

Patients who underwent FCSEMS between January 1, 2018, and December 31, 2019, in our ERCP unit were included. Endoscopic retrograde cholangiopancreatography procedure reports were found by searching for "covered metallic stent" from the EndoCam operating system. Patients who have been inserted a partially covered or uncovered metallic stent were excluded from the study. Then, the patients' age, gender, indication of FCSEMS insertion, previous ERCP procedure status, and ERCP procedure requirement after removal of the FCSEMS stent were recorded

by examining the patient files one by one. Approval for the study was obtained from the ethics committee of Ege University (Date: August 04, 2022, Number: 22-8T/39). All patient information was kept confidential, and the study was conducted according to the principles of the Declaration of Helsinki.

Statistical Analysis

Statistical Package for the Social Sciences version 22.0 (IBM SPSS Corp.; Armonk, NY, USA) was used for data analysis. Categorical data were presented as numbers and percentages, whereas numerical data were presented as median (minimum value−maximum value).

RESULTS

There were 149 patients in the study. The mean age was 57.44 ± 16.86 years. About 46.3% of the patients were women. Benign biliary stenosis in the common bile duct was the first with a rate of 36.2% in indications. Malignant biliary stenosis was in the second place at 11.4%, and post-transplant anastomotic stenosis was in the third place at 8.7%. Other indications were biliary stricture due to chronic pancreatitis (8.1%), bile leakage after cholecystectomy (8.1%), type 2 perforation (6%), hemorrhage due to sphincterotomy (6%), unremovable common bile duct stone (4%), and biliary stricture due to portal biliopathy 3.4% (Table 1). About 37.6% of the patients had a previous history of ERCP. It was observed that a second ERCP session was performed after the removal of the FCSEMS in 37.6% of the patients. Twenty-two (14%) patients did not come to our unit for the second session. In 7 (5%) of 127 patients who come to our unit, there was no stent in the papilla seen either with endoscopy or fluoroscopy (stent migration). The median time between insertion and removal sessions was 34 days (min: 5 days, max: 417 days) in patients (80%) whose FCSEMS was removed in our center. While the median time between the insertion and removal of the FCSEMS used for benign biliary stenosis was 49 days (min: 49, max: 417), this period was 57 days (min: 19, max: 372) in post-transplant anastomotic stenosis, 60 days (min: 22, max: 280) in biliary stricture due to chronic pancreatitis, 20 days (min: 5, max: 82) in postoperative bile leakage, 23 days (min: 9, max: 54) for perforation, and 28 days (min: 7, max: 130) for sphincterotomy bleeding.

Table 1. Clinical Characteristics of 149 Patients Underwent a Fully Covered Self-Expandable Metallic Stent

Age (years ± SD)	**57.44 ± 16.86**
	n (%)
Sex	
Male	80 (53.7)
Indications	
Benign biliary stricture	54 (36.2)
Malignant biliary stricture	17 (11.4)
Anastomotic stricture	13 (8.7)
Chronic pancreatitis	12 (8.1)
Bile leak	12 (8.1)
Perforation	9 (6)
Post-sphincterotomy hemorrhage	9 (6)
Choledocholithiasis*	7 (4.7)
Portal biliopathy	5 (3.4)
Others	11(7.4)
Intervals (between insertion and removal)	Median (min−max)
All	34 (5-417)
Benign biliary stricture	49 (49-417)
Malignant biliary stricture	16 (11-108)
Anastomotic Stricture	Lack of data
Chronic pancreatitis	60 (22-280)
Bile leak	20 (5-82)
Perforation	23 (9-54)
Post-sphincterotomy hemorrhage	28 (7-130)

*These patients with a previous cholecystectomy operation have benign biliary strictures located distally to biliary stones.

DISCUSSION

Benign biliary strictures are caused by chronic inflammation, collagen deposition, and fibrosis. The most common benign biliary strictures are postoperative strictures, stenoses due to chronic pancreatitis, and strictures due to chronic inflammation.[9] Endoscopic treatment in chronic pancreatitis includes stenting of the main pancreatic duct to provide pancreatic decompression and intervention for stenosis due to inflammation or fibrosis in the common bile duct. Biliary stenosis due to chronic pancreatitis is the result of recurrent inflammation and consequent fibrosis. Biliary stenosis occurs in 30%-40% of chronic pancreatitis cases. The use of FCSEMS in the management of biliary tract strictures due to chronic pancreatitis is also supported by studies. In a randomized study, the rates of non-relapse within 2 years after stent removal were found to be the same between multiple plastic stents (MPS) and FCSEMS (88.0% vs. 90.9%, respectively), and treatment-related morbidity rates were also similar in this study (23.3%. vs. 28.6%, respectively).[10] In our study, the mean time between the insertion and removal of the FCSEMS used for biliary stricture due to chronic pancreatitis is 89 ± 75.41 days. In the literature, a review has shown that covered self-expandable metallic stents provide better results than MPS in biliary strictures due to chronic pancreatitis, but this review included non-comparative studies and some studies included single plastic stents in patients.[11] The European Society of Gastrointestinal Endoscopy guidelines recommend the temporary use of FCSEMS or MPS for the treatment of biliary strictures due to chronic pancreatitis.[12]

MAIN POINTS

With this study

- We obtain the indications of the fully covered self-expandable metallic stents.
- We obtain the time intervals between insertion and removal sessions of the fully covered self-expandable metallic stents.
- We obtain the complication ratios of the fully covered self-expandable metallic stents in our unit.

Postoperative biliary strictures, which correspond to an important group among benign biliary strictures, occur most frequently after cholecystectomy and biliary tract surgery. The application of plastic stents is an effective therapeutic method in such strictures. In general, MPS are required. A high clinical success ratio and low stricture recurrence ratio are seen with plastic stents for up to 1 year by changing them at 3-4 monthly intervals.[13] However, plastic stent occlusion, which requires endoscopic stent replacement within 3-4 months, is an important limitation due to the overall cost and necessity for patient compliance. Fully covered self-expandable metallic stents can extend to a larger diameter, and their chemical coating limits tissue growth. A single FCSEMS can be left in place for extended periods of time without the need for stent replacement. In a retrospective study involving 69 patients comparing FCSEMSs and plastic stents in postoperative

strictures, findings showed a similar success rate and stenosis recurrence (16% in the plastic stent group and 22% in the covered metal stent group).[14] On the other hand, the median stenting time was 5.2 months in the FCSEMS group and was 10.7 months in the plastic stent group. The trial highlights the use of FCSEMSs as a practical and effective alternative to endoscopic treatment with plastic stents in postoperative biliary strictures.

Biliary anastomotic strictures constitute 80% of stenosis seen after liver transplantation. Anastomotic strictures occur 1-2 months after the operation and are characterized as short biliary stenosis. Current strategies for treating anastomotic strictures include balloon dilation and endoscopic stenting. In a meta-analysis comparing the FCSEMS with plastic stents in the treatment of anastomotic stenosis after liver transplantation, there was no significant difference in stenosis treatment, complications, and recurrence.[15] However, it was observed that the treatment time in the use of FCSEMSs was significantly shorter than in the other group. In our unit, biliary anastomotic stenosis was observed in 8.7% of liver transplanted cases in the indications of FCSEMSs.

Bile leakage consists due to damage to the biliary tract due to cholecystectomy, ERCP, hepatectomy, other hepatobiliary operations, liver transplantation, or after percutaneous interventions. Bile leakage occurs within 1 week postoperatively and is usually located at the cystic duct stump. In small bile duct leaks, low drainage output is seen and they resolve on their own without an intervention. In contrast, in complex bile leaks, persistent bile discharge is seen. The standard approach is biliary sphincterotomy and plastic stenting to abate the transpapillary pressure gradient.[16] As a result, bile will flow into the intestinal lumen with the stent and the stent will close the bile leakage. Complex bile leaks that occur in anastomotic bile leaks after liver transplantation or cholecystectomy do not respond to the plastic stent. These states are used because FCSEMS will effectively seal the leak field. In a study of complex post-transplant bile leaks treated with an FCSEMS, long-term leak control was achieved with FCSEMSs.[17] However, biliary strictures were observed in 35% of patients in the FCSEMS group after the stent removal. It is thought that FCSEMSs cause stricture formation due to bile duct compression and related ischemia. In our unit, the rate of use of FCSEMS due to a bile leakage was 8.1%.

In biliary endoscopic sphincterotomy, the biliary sphincter and the intraduodenal segment of the common bile duct are resected. Usually, it is a necessary procedure for ERCP Bleeding is an important complication of biliary sphincterotomy. Most bleeding after sphincterotomy is minor and resolves spontaneously. However, significant bleeding cases that require blood transfusion support and emergency endoscopic intervention are also seen. While methods include injection, balloon tamponade, and mechanical (eg, embolization) approaches, hemostasis can also be provided with the tamponade effect with the use of FCSEMS. A retrospective study to date has included 67 patients with bleeding after sphincterotomy and compared FCSEMSs with other treatments.[18] In this study, the FCSEMS group had a significantly lower bleeding rate (0.66 g/dL) than the other group (1.98 g/dL). In our study, the rate of use of FCSEMSs due to post-sphincterotomy bleeding was 6%.

In the study of Shayan et al, 40% bile leakage, 31% bleeding, and 21% perforation were seen in the indications of FCSEMS. In our study, FCSEMSs were mostly used in benign strictures.[19] Stents were removed in all 87 patients in their study. However, stent migration was observed in 4% of patients in our study. In the Shayan study, the median stenting time was 9 weeks in patients with bile leakage, 3 weeks in patients with bleeding and 9.5 weeks in patients with perforation. The median time between insertion and removal sessions in our unit was 34 days (min: 5 days, max: 417 days). The mean time between the application and removal of the FCSEMSs used for a benign biliary stenosis was 75.93 ± 84.16 days, while this time was 27.13 ± 17.1 days for perforation and 40.43 ± 41.83 days for sphincterotomy hemorrhages.

The limitations of this study are the retrospective design and the absence of a control group. In addition, long-term results are absent. Fully covered self-expandable metallic stents are used to treat a variety of benign and malignant biliary pathological condition, including biliary leak, bleeding after sphincterotomy, and strictures. A chemical coating prolongs stent patency, reducing the risk of tissue hyperplasia and tumor growth. However, FCSEMSs may face stent migration issues that can be addressed with modifications, including enlarged ends and anchor flaps.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of Ege University (Date: August 04, 2022, Number: 22-8T/39).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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REFERENCES

1. Soehendra N, Reynders-Frederix V. Palliative bile duct drainage - a new endoscopic method of introducing a transpapillary drain. *Endoscopy*. 1980;12(1):8-11. [CrossRef]
2. Huibregtse K, Cheng J, Coene PP, Fockens P, Tytgat GN. Endoscopic placement of expandable metal stents for biliary strictures--a preliminary report on experience with 33 patients. *Endoscopy*. 1989;21(6):280-282. [CrossRef]
3. Brandabur JJ, Kozarek RA, Ball TJ, et al. Nonoperative *versus* operative treatment of obstructive jaundice in pancreatic cancer: cost and survival analysis. *Am J Gastroenterol*. 1988;83(10):1132-1139.
4. Raikar GV, Melin MM, Ress A, et al. Cost-effective analysis of surgical palliation *versus* endoscopic stenting in the management of unresectable pancreatic cancer. *Ann Surg Oncol*. 1996;3(5):470-475. [CrossRef]
5. Lee TH, Lee SJ, Moon JH, Park SH. Technical tips and issues of biliary stenting, focusing on malignant hilar obstruction. *Minerva Gastroenterol Dietol*. 2014;60(2):135-149. [CrossRef]
6. Lee MJ, Dawson SL, Mueller PR, Krebs TL, Saini S, Hahn PF. Palliation of malignant bile duct obstruction with metallic biliary endoprostheses: technique, results, and complications. *J Vasc Interv Radiol*. 1992;3(4):665-671. [CrossRef]
7. Levy MJ, Baron TH, Gostout CJ, Petersen BT, Farnell MB. Palliation of malignant extrahepatic biliary obstruction with plastic *versus* expandable metal stents: an evidence-based approach. *Clin Gastroenterol Hepatol*. 2004;2(4):273-285. [CrossRef]
8. Tham TC, Carr-Locke DL, Vandervoort J, et al. Management of occluded biliary Wallstents. *Gut*. 1998;42(5):703-707. [CrossRef]
9. Wilson C, Auld CD, Schlinkert R, et al. Hepatobiliary complications in chronic pancreatitis. *Gut*. 1989;30(4):520-527. [CrossRef]
10. Haapamäki C, Kylänpää L, Udd M, et al. Randomized multicenter study of multiple plastic stents *vs.* covered self-expandable metallic stent in the treatment of biliary stricture in chronic pancreatitis. *Endoscopy*. 2015;47(7):605-610. [CrossRef]

11. Siiki A, Helminen M, Sand J, Laukkarinen J. Covered self-expanding metal stents may be preferable to plastic stents in the treatment of chronic pancreatitis-related biliary strictures: a systematic review comparing 2 methods of stent therapy in benign biliary strictures. *J Clin Gastroenterol*. 2014;48(7):635-643. [CrossRef]
12. Dumonceau JM, Tringali A, Papanikolaou IS, et al. Endoscopic biliary stenting: indications, choice of stents, and results: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline - Updated October 2017. *Endoscopy*. 2018;50(9):910-930. [CrossRef]
13. Bergman JJ, Burgemeister L, Bruno MJ, et al. Long-term follow-up after biliary stent placement for postoperative bile duct stenosis. *Gastrointest Endosc*. 2001;54(2):154-161. [CrossRef]
14. Wu J, Zhou DX, Wang TT, Gao DJ, Hu B. A new fully covered self-expandable metal stent for the treatment of postsurgical benign biliary strictures. *Dig Dis Sci*. 2017;62(9):2550-2557. [CrossRef]
15. Facciorusso A, Rosca EC, Ashimi A, et al. Management of anastomotic biliary stricture after liver transplantation: metal *versus* plastic stent. *Ann Gastroenterol*. 2018;31(6):728-734. [CrossRef]
16. Shah JN. Endoscopic treatment of bile leaks: current standards and recent innovations. *Gastrointest Endosc*. 2007;65(7):1069-1072. [CrossRef]
17. Martins FP, Phillips M, Gaidhane MR, Schmitt T, Kahaleh M. Biliary leak in post-liver-transplant patients: is there any place for metal stent? *HPB Surg*. 2012;2012:684172. [CrossRef]
18. Cochrane J, Schlepp G. Comparing endoscopic intervention against fully covered self-expanding metal stent placement for post-endoscopic sphincterotomy bleed (CEASE Study). *Endosc Int Open*. 2016;4(12):E1261-E1264. [CrossRef]
19. Irani S, Baron TH, Law R, et al. Endoscopic treatment of nonstricture-related benign biliary diseases using covered self-expandable metal stents. *Endoscopy*. 2015;47(4):315-321. [CrossRef]