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CASE REPORT

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Evaluation of EGIS Biliary Stent

Double Bare Type and Double Covered Type

for the Treatment of Middle and Lower Part Malignant Bile Duct Stenosis

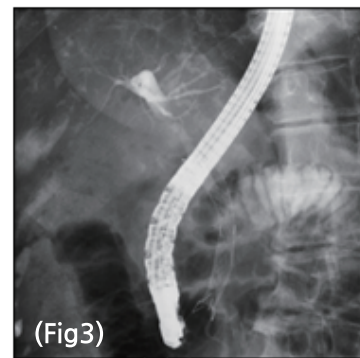
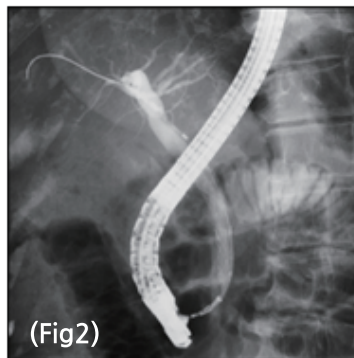
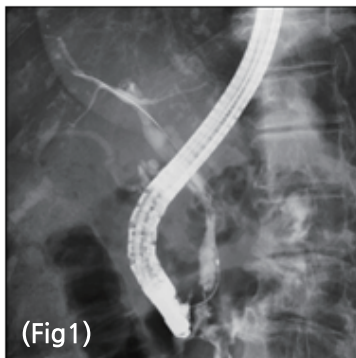
Headline

Biliary drainage for irremovable middle and lower part of bile duct stenosis is an important treatment for improving and preventing obstructive jaundice and introducing stable chemotherapy thereafter. Trans papillary drainage is recommended as the first choice in drainage method, and stents to place for drainage purposes include plastic stents (PS) and self-expandable metallic stents (SEMS). In the case of irremovable middle and lower part of bile duct stenosis, SEMS is more likely to be the first choice than PS in expectation of long patency, but various discussions have been continuing on the feasibility of covered or uncovered stent in SEMS. The EGIS biliary stent was approved for use in February 2014, and is characterized by a double structure with a double stent different from the existing SEMS. It is expected that the ingrowth of the tumor can be prevented because the mesh interval is

smaller than that of the existing single stent. In addition, because of the double structure, it is expected to reduce the complications such as occlusion due to stress on the bile duct wall, pancreatitis due to compression of the pancreatic duct by inhibiting axial force. We will report on the usefulness of the EGIS stent from our experience.

【Points on placing SEMS】

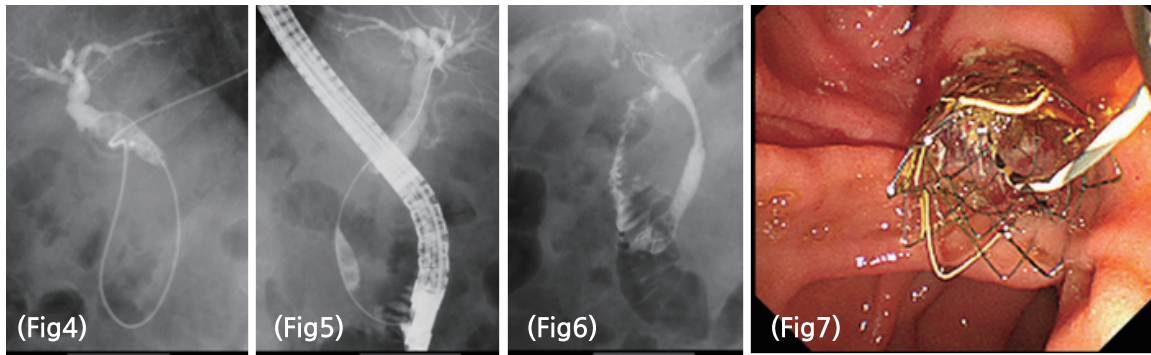
First, select an anterior segmental branch where the guide wire becomes a straight line so that the load avoids the delivery system. (Fig. 1). A length with 1-2 cm long stent is selected for the liver and duodenum rather than the stent with a length of the bile duct stenosis. If you do not have enough papilla space at the bottom of the stent, choose a stent about 1 cm from the papilla. In other words, it is necessary to pay attention to the shortening of the stent so that the stent does not expand in the intrahepatic bile duct. In addition, select the stent with an appropriate diameter (8mm · 10mm) by measuring the diameter of the bile duct, where the stent is placed, using cholangiography. It must be checked because it may be pressed against the stent above the diameter of the bile duct, and it may be a cause of granulation in the uncovered stent, cholecystitis and pancreatitis in the covered stent. After that, the delivery system is carefully deployed while maintaining the distance between the stent and the stenosis. To avoid the delivery system being difficult to deploy by getting kinked near the lower end of the stent, the delivery system should position it as if it's drawing a parabola so that the load is avoided. (Fig. 2). Deploy by checking the position of the stent deployment, and the distance between the scope and the papilla to the end.



Case 01 : Double covered stent placement for bile duct stenosis due to pancreaticobiliary cancer

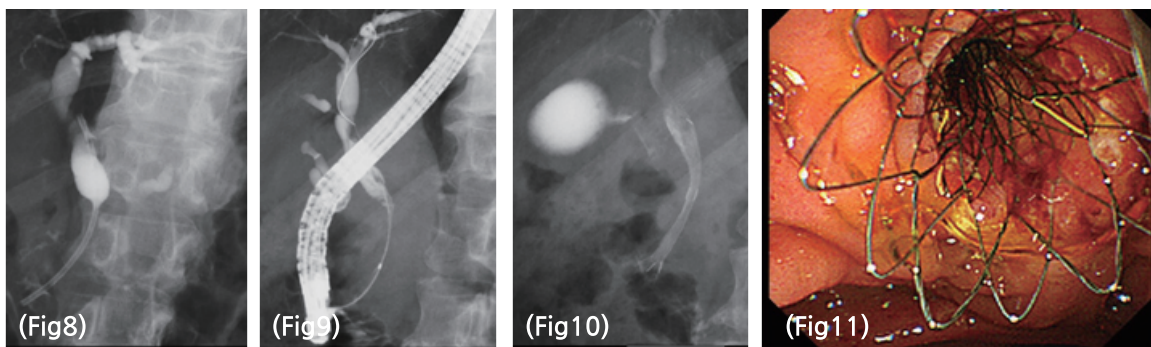
78 years old female. The patient was admitted to the hospital with jaundice, and at the time of consultation, the CT showed obstructive jaundice due to suspicion of bile duct stenosis with pancreatic tumor. Emergency ERCP was performed on the day of consultation, NBD tube was placed (Fig. 4), and then EUS-FNA was used to diagnose pancreatic cancer. EGIS was placed in the stenosis of the bile duct a few days after the operation was judged to be difficult. At the time of admission, the inserted NBD tube was removed and cholangiography was performed to confirm the location and the length of the stenosis. We used the guide wire and checked the length of the stent on the side of the papilla.

EST was performed to prevent pancreatitis, and a double covered stent of 10 mm × 80 mm was placed in accordance with the stricture length. When placement, take it out a little more to the liver than the planned position, then gradually extend to the end position at the placement position and end it with 1cm from the papilla. (Fig. 5, 6, 7).



Case 02 : Double bare stent placement to bile duct stenosis according to pancreaticobiliary cancer

70 years old male. The patient was admitted to the hospital with a jaundice. During the examination, the CT showed obstructive jaundice and multiple metastasis due to suspicion of bile duct stenosis with pancreatic tumor. Emergency ERCP was performed on the day of the visit, and the RBD tube was placed. (Fig. 8) After that, we diagnosed pancreatic cancer by EUS-FNA. A few days later, EGIS was placed in the bile duct stenosis. Removed the inserted RBD tube at admission and cholangiography was used to check the location and length of the stenosis. We used the guide wire to check the length of the stent placement on the side of the papilla as shown in Case 1. EST was performed for the prevention of cholecystitis, and a double bare stent of 10 mm × 60 mm was placed in accordance with the stenosis. (Fig. 9, 10 and 11).



Results of EGIS (Double bare type and Double covered type) in the hospital

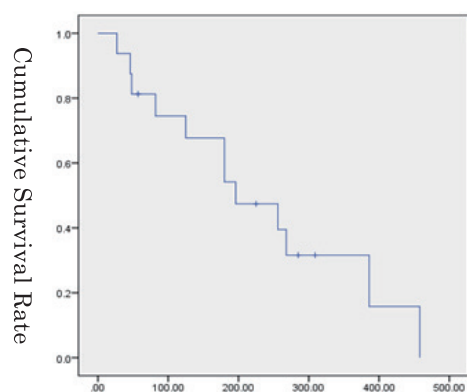
【Target】

We reviewed 16 cases (9 cases of male, 7 cases of female, 60-90 years of age) using EGIS biliary stent for bile duct stenosis from May 2015 to January 2017 and reviewed the success rate, patency period, and accidental disease.

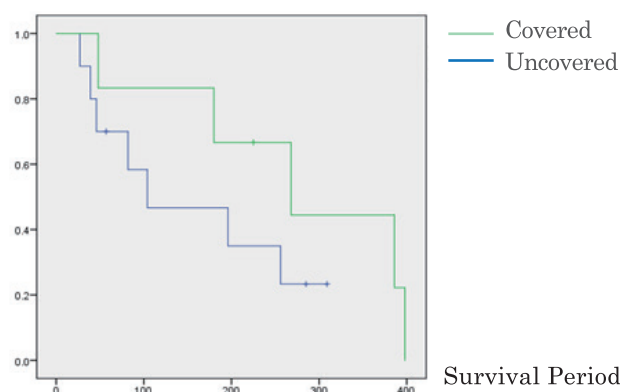
【Result】

The origin of the stenosis is 13 cases of pancreaticobiliary cancer, and 3 cases of bile duct cancer. There were 10 cases of Double Bare type and 6 cases of Double Covered type.

Double Bare Type	Success Rate 100%	Stent Occlusion : 2 Case
Double Covered Type	Success Rate 100%	Stent Occlusion : 1 Case



Average Survival Period : 233.9 days



Average Patency Period : 214.7 days

The cumulative survival rate and time to recurrent biliary obstruction (TRBO) after placing EGIS on the Fig. was assessed by Kaplan-Meier. At the time of death or stent occlusion, the end point of the TRBO was defined. The median survival period was 196 days, and the median patency period was 268 days with covered, 104 days with uncovered. There was a difference in patency period between covered and uncovered because the time of death was assessed as end point, but there was no significant difference between survival rate and individual patency rate.

【Result】

The procedure success rate was both 100%. There was no evidence of an accidental disease. There were only 3 cases of occlusion, 1 case of ingrowth and 1 case of overgrowth in Double Bare type, 1 case of obstructive jaundice due to sludge in Double Covered type. At the current evaluation, there is no difference between the normal single stent and the survival period, because it was patented to death in most cases.

【Summary】

Various types of SEMS have been developed and sold, and can be largely classified according to the presence of the cover and the stent mesh structure, and it is necessary to understand the characteristics and select. The covered type has few ingrowth and can be removed. However, frequent accidental disease can cause stent migration or cholecystitis and pancreatitis. Uncovered type, unlike covered type, has less migration after placement, but the incidence of ingrowth increases. In addition, there are Radial force, Axial force, and Shortening ratio, which are important factors that determine the characteristics of SEMS. The stent structure has a twisted shape and a laser cut shape, and the twisted shape has a high radial force, axial force, and shortening ratio. At present, there are no definite stents for Middle and Lower Part Malignant Bile Duct Stenosis, and various theories about the patency period of the covered type and the uncovered type are continuing. There is also a review of righteousness between the twisted shape and the laser cut shape. The EGIS used is a twisted double stent. The double structure is expected to reduce the mesh spacing, inhibit the migration of the stent, and prevent ingrowth of the tumor. In addition, it is expected that the axial force can be increased according to the double structure by lowering the wires by densification, preventing great stress on the bile duct wall, and lowering the probability of pancreatitis due to compression of the pancreatic duct. On the case of the hospital, there was no stent migration, cholecystitis, or pancreatitis associated with the double stent. If a double stent is used to prevent ingrowth and expands the patency rate compared to a single stent, it will be a stent with the advantages of uncovered type and covered type in combination with the prevention of stent migration that may easily occur with the original covered type. Therefore, I think that the current era where the development of a covered stent is required can be a waiting stent for Middle and Lower Part Malignant Bile Duct Stenosis. I would like to increase the number of cases in the future to determine the usefulness and safety of the double stent.



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