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EGIS Biliary Stent

Usefulness of EGIS Biliary Double Bare Stent

for Middle to Lower Part Malignant Biliary Obstruction

Metallic Stent Placement of Middle to Lower Part Malignant Bile Duct Obstruction -covered? uncovered?

If a self-expandable metallic stent (SEMS) is installed for unresectable middle-to-lower malignant biliary obstruction (DMBO), In past RCT reports 1 and 2 comparing uncovered SEMS (USEMS) and covered SEMS (CSEMS), many facilities are expected to place CSEMS that can expect a long patency. CSEMS is thought to be able to expect longer patency than USEMS as it prevents ingrowth. However, since CSEMS has more migration or sludge formation than USEMS and risk of causing gallbladder, pancreatic duct, and pancreatitis, there are facilities where USEMS is still used for DMBO. (Table1)

	CSEMS	USEMS
• Patency	○	>or=
• Dysfunction		
Ingrowth	◎	<<
Overgrowth		>
Migration		>> ◎
Sludge		> ○

Table1. CSEMS vs. USEMS

Uncovered also prevents ingrowth?!

EGIS Biliary Double Bare Stent (EGIS-DBS; Sumitomo Bakelite Co., Ltd.) is a USEMS, which is the smallest mesh in the world, by making two sides of USEMS, one side 2mm mesh, one side 1mm mesh. (Figure 1) This concept is that the USEMS's traditional characteristics of sludge formation and ingrowth are small, and that it does not block the gallbladder or pancreatic duct, thus preventing ingrowth with a fine mesh.

In fact, EGIS-DBS and general USEMS (Single Bare Stent (SBS); EGIS-DBS was reported to have a lower ingrowth and longer duration than the other two types of SBS in RCTs comparing S & G (SBSs) and third-party products (SBSt). 3) (Figure2, Table2 Furthermore, the multicenter RCT, which we are currently participating in, is underway and awaiting results of the most interesting trial comparing the lifetime of EGIS-DBS vs. CSEMS.

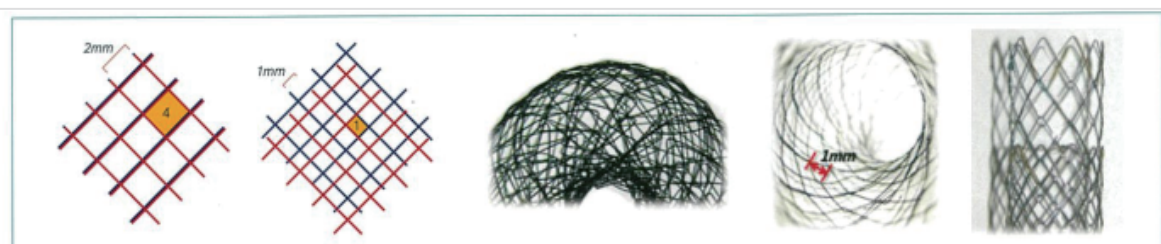


Figure1. EGIS-DBS

	DBS(n=24)	SBSt(n=23)	P value [†]	SBSs(n=24)	P value [†]
Technical success, n(%)	24(100%)	23(100%)	NS	24(100%)	NS
Time to stent occlusion, mean ± SD, days	212(±152)	116(±79)	0.01	124(±98)	0.022
Rate of stent occlusion, n(%)	2(8.3%)	10(43.5%)	0.008	11(45.8%)	0.008
Cause of occlusion, n(%) [*]					
Tumor ingrowth	1(4.2%)	7(30.4%)	0.023	9(37.5%)	0.010
Tumor overgrowth	2(8.3%)	2(8.7%)	NS	1(4.2%)	NS
Sludge	2(8.3%)	4(17.4%)	0.416	4(16.7%)	0.666

Table2. DBS vs. SBS

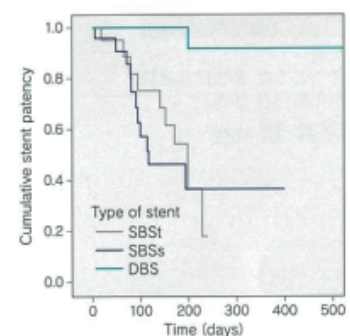


Figure2. DBS vs. SBS
開存期間のKaplan-Meier曲線

High conformability

Another feature of the EGIS-DBS is low axial force (AF). If the SEMS with high AF is placed in a bend with severe bending, the kinking as shown in Figure 3 may occur, so lower AF is better. EGIS-DCS is also characterized by low AF. Normally, a simple cover on SEMS increases AF, but EGIS-DCS does not increase AF because it has loosely sandwiched a silicon film

between two overlapping SEMs with low AF, and flexibility is high. When creating a tightly meshed USEMS, AF increases to make the mesh smaller with a single stent, EGIS-DBS can maintain low AF because it creates a small mesh by superimposing two USEMS with relatively large mesh with low AF. (Table 3). Therefore, it also exhibits high conformability to the curved bile ducts. EGIS also has a CSEMS EGIS biliary double covered stent (EGIS-DCS) which is partially CSEMS. At this point, it is believed that it is useful for cases with high risk of ingrowth because there is evidence to prevent ingrowth surely because it is CSEMS.



	AF
SBS (Mesh 1.5mm)	0.40-0.49N
DBS (Mesh 1.0mm)	0.26-0.29N

Table 3.
SBSとDBSのAFの比較

	AF
DBS	0.26-0.29N
DCS	0.25-0.28N

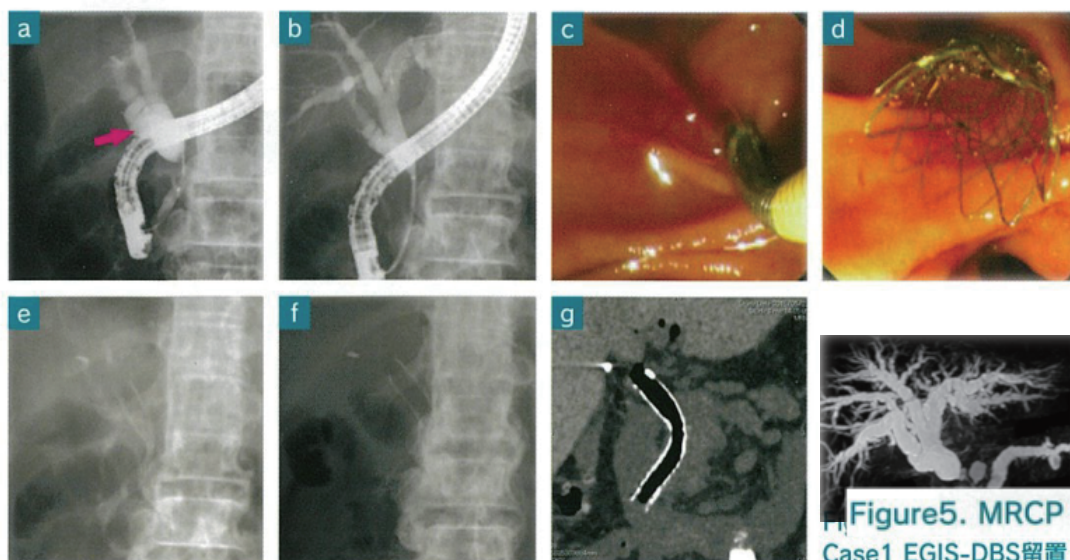
Table 4.
DBSとDCSのAFの比較

Experience in Hospital

Currently, there are 27 cases of DMBO, EGIS biliary stent (DBS14 case, DCS13 case) in the gastroenterology department of Tane General Hospital. The average time to recurrent biliary obstruction (the death case is the patency period until the date of death) was 146 ± 137 days. As of August 2017, 89.5% (17/19) of patients who died in the past did well as SEMs without experiencing recurrent biliary obstruction until death. At this time, there was no difference in cumulative stent patency between DBS and DCS. (Figure 4) The cases were 1 case of pancreatitis after ERCP (DBS 1 case), and 2 cases of cholecystitis (DCS 2 case).

Case Presentation: Case 1

82 years old male, MRCP of DMBO according to pancreas head cancer revealed the lower bile duct to have curved stenosis due to tumor exclusion and the upper biliary duct was remarkably enlarged. Furthermore, the right hepatic duct was a branch in the lower position in the central bile duct. (Figure 5) The points to consider what type of SEMs to install in this case is ① Do not block the right hepatic duct of the lower branch, ② It should be pancreatic cancer and is likely to be ingrowth, ③ The risk of kinking is higher than that of SEMs with high conformability because bending of the bile duct is severe. These may be the cases. In this case, we have decided to install EGIS-DBS in SEMs, where ① is a target condition, and ②, ③ is also a possibility to solve the problem. The shape of cholangiography of the bile duct at the time of ERCP was MRCP. (Figure 6a) EGIS-DBS, 10mm diameter, 8cm length was placed across the papilla. Insertion of 8Fr delivery sheath is no problem, and handling of the handle at deployment is relatively smooth. During deployment, locate with reference to the radiopaque marker at the time of fluoroscopy and the yellow marker at the endoscope. (Figure 6b,c) It is a Braided SEMs, but the shortening rate is as low as 20% and there is almost no jumping at the bottom of the stent at the completion of the deployment, so the length of the stent from the papillary can be accurately determined. (Figure 6d) Immediately after placement, the dilatation of the stenosis was not enough, but it was placed in the shape of a curved biliary duct and the contrast agent of Right hepatic duct was drained down. (Figure 6e) In Xp and CT after 1 week, EGIS-DBS showed good conformability even in bifurcated bile ducts with good stenosis enlargement. (Figure 6f,g)



Case Presentation: Case2

57 years old male, who had middle-to-lower malignant biliary obstruction (DMBO) by the lymph gland is metastasized because of gallbladder cancer. Through MRCP the angel of middle-to-lower biliary seems to be S shape like Case①. (Figure7a) EGIS-DCS, 10mm diameter, and 9 cm were installed across the papilla. Immediately after placement, the stenosis was not enlarged, but it was installed in the form of a curved biliary duct. (Figure7b) After one week, EGIS-DCS was sufficiently extended by XP and CT and conformability was good. (Figure7c.d)

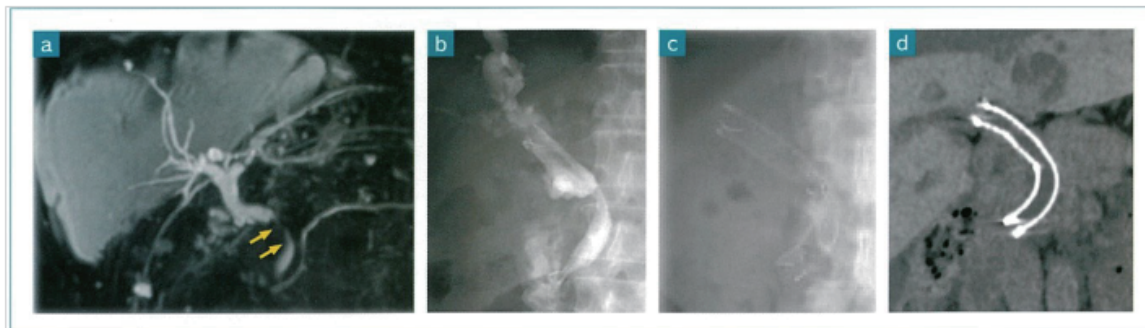


Figure7. EGIS-DCS留置

Conclusion

SEMS placement points for DMBO and the usefulness of EGIS biliary stent were established. The EGIS is a promising stent with good conformability to the biliary tract with a moderate degree of radial force and low axial force that is gradually and fully extended. However, as described earlier, the result of the ongoing multicenter RCT or removability is fully compatible with CSEMS and proper use in accordance with the purpose is a subject to be examined in the future.

[References]

- 1) Isayama H et al. *Gut*. 2004; 53(5): 729-34.
- 2) Kitano M et al. *Am J Gastroenterol*. 2013; 108(11): 1713-22.
- 3) Lee HJ et al. *Surg Endosc*. 2017; 31(8): 3159-67.