Side Anchoring Plastic Stent to a Fully Covered Self-expandable Metal Stent in distal malignant biliary obstruction

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Disclosures

There is no conflict of interest in this study

Purpose of Study

1. To assess the efficacy of additional side-by-side plastic stent (PS) placement to Fully Covered Self-expandable Metal Stent (FCSEMS)
2. And the effect on stent-related adverse events

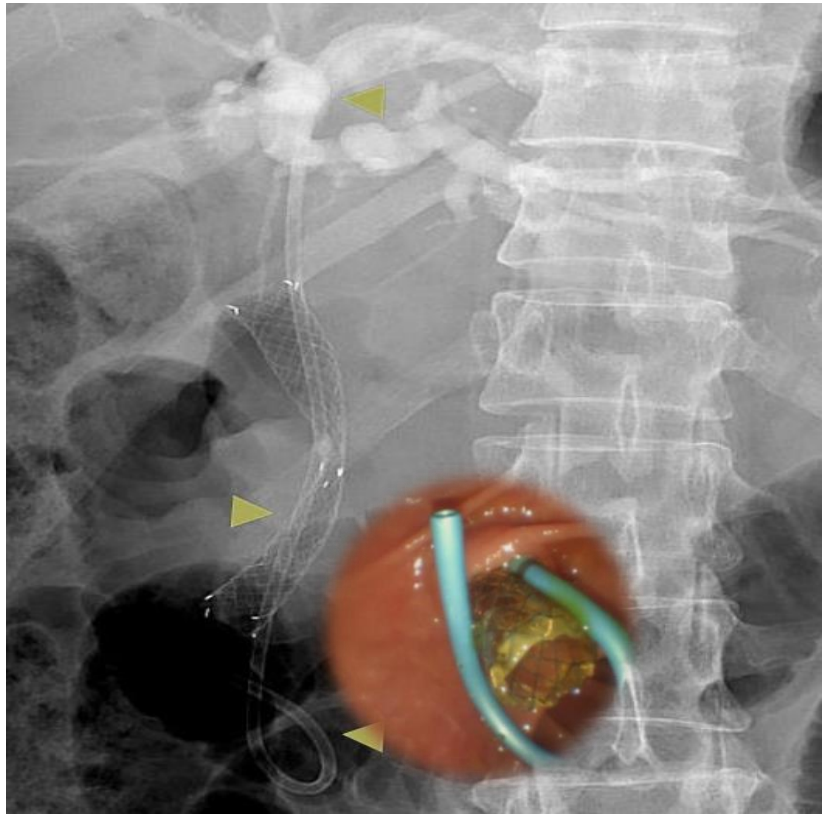
Study Design & Patients

- Design
  - Multicenter, retrospective, comparative study
  - Two tertiary institutions (SNUH, NCC)
  - January 2017 ~ December 2019

- Patients
  - Underwent endoscopic retrograde biliary drainage for unresectable malignant biliary obstruction
  - Exclusion: previous uncovered SEMS, hilar stricture, benign stricture

Procedures & outcomes

- Procedures
  - Experimental group (Figure)
    - A 7F double pigtail PS was placed prior to SEMS
    - Proximal end of PS was located to the intrahepatic duct
    - FCSEMS with sufficient coverage of the stricture
  - Control group: FCSEMS only



- Outcomes
  - Primary: stent patency (time to stent dysfunction)
  - Secondary: rate of stent dysfunction, occlusion and migration, adverse events

Baseline characteristics

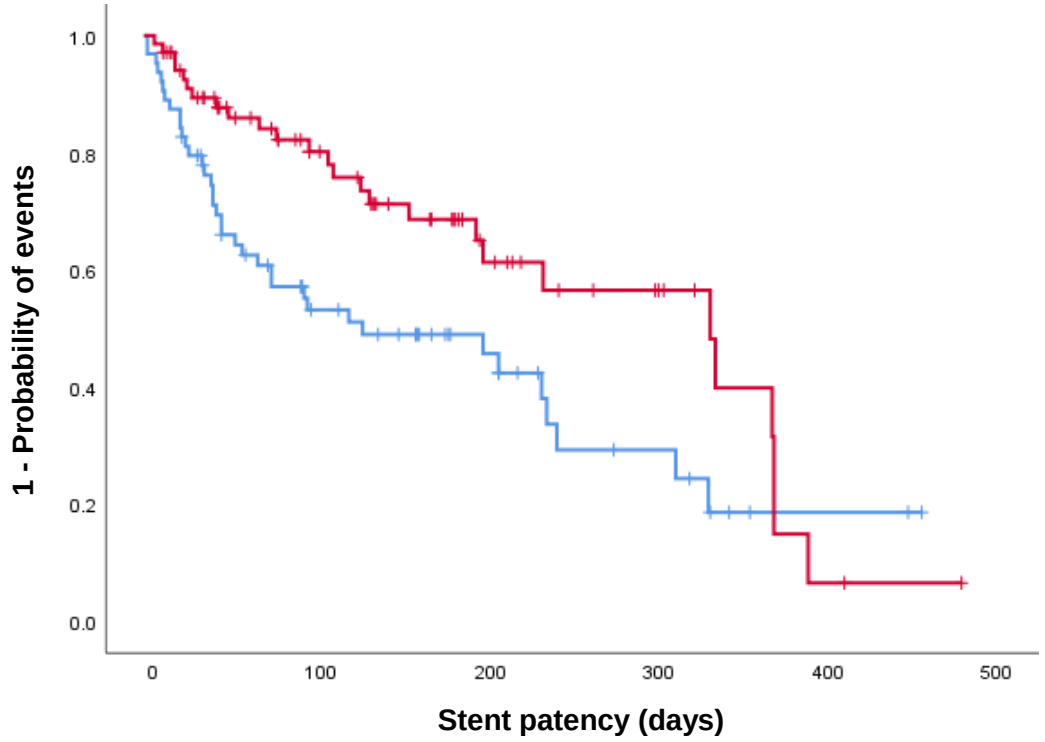
	FC-SEMS only N = 70	Side PS anchoring N = 76	P value
Age, median (range)	65 (33-88)	66 (37-90)	0.391
Sex (male, %)	43 (61.4)	48 (63.2)	0.829
Previous ERBD stent	29 (41.4)	32 (42.1)	0.934
Temporary PTBD	5 (7.1)	7 (9.2)	0.65
s/p cholecystectomy	4 (5.7)	3 (3.9)	0.71
Tumor size, median (mm)	31 (11-90)	30 (10-55)	0.841
Tumor ≥3cm	38 (54.3)	45 (59.2)	0.548
Stricture length, median (mm)	14 (7-51)	18 (8-55)	<0.001
Length ≥2cm	16 (22.9)	31 (40.8)	0.021
Cancer type			
Pancreatic cancer	57 (81.4)	53 (69.7)	0.121
Biliary tract (CBD, GB, AoV)	5 (7.1)	14 (18.4)	
metastatic	8 (11.4)	9 (11.8)	
Metastatic disease	33 (47.1)	43 (56.6)	0.254
Peritoneal seeding	9 (12.9)	13 (17.1)	0.473
Chemotherapy	59 (84.3)	68 (89.5)	0.352
Cystic duct on cholangiogram	45 (64.3)	40 (52.6)	0.154
PEP	6 (8.6)	11 (14.5)	0.267
MS ≥ 6cm	21 (30.0)	37 (48.7)	0.021

Comparison of Efficacy and Safety

	FC-SEMS only N = 70	Side PS anchoring N = 76	P value
Dysfunction	37 (52.9)	26 (34.2)	0.023
Migration	18 (25.7)	8 (10.5)	0.017
Occlusion	13 (18.6)	17 (22.4)	0.571
Adverse event	15 (21.4)	18 (23.7)	0.745
pancreatitis	2 (2.9)	0 (0.0)	0.228
cholangitis/abscess	7 (10.0)	10 (13.2)	0.552
cholecystitis	5 (7.1)	6 (7.9)	0.863
bleeding	2 (2.9)	2 (2.6)	0.999
perforation	1 (1.4)	0 (0.0)	0.479
Adverse event grade ≥ 2	10 (14.3)	9 (11.8)	0.661

Stent patency & Factors

Stent patency



Stent patency	FC-SEMS only	Side PS anchoring	P value (Log-rank)
Days, median (95% CI)	206 (78 – 334)	332 (206 – 458)	0.019

Factors affecting stent patency*

Factors	Univariable (95% CI)	P	Multivariable (95% CI)	p
Side plastic stent	0.55 (0.33-0.91)	0.021	0.53 (0.31-0.92)	0.025
Tumor size	1.04 (1.01-1.06)	0.002	1.03 (1.01-1.05)	0.009
Stricture length	1.01 (0.98-1.03)	0.551	1.01 (0.99-1.04)	0.381
Stricture site	1.23 (0.68-2.23)	0.487		
Chemotherapy	0.76 (0.36-1.60)	0.465		
P-seeding	1.04 (0.53-2.06)	0.900		
Cancer type	1.16 (0.81-1.64)	0.421		

* Uni-/Multi-variate Cox regression analysis

Summary & Conclusion

Side anchoring PS to FCSEMS

	FC-SEMS only	Side PS anchoring	P value
Dysfunction (%)	37 (52.9)	26 (34.2)	0.023
Migration (%)	18 (25.7)	8 (10.5)	0.017
Occlusion (%)	13 (18.6)	17 (22.4)	0.571
Adverse event (%)	15 (21.4)	18 (23.7)	0.745
Stent patency (days)	206 (78 – 334)	332 (206 – 458)	0.019

Side-by-side placement of PS could decrease the risk of stent dysfunction of FCSEMS without a significant increase of adverse events rate in distal malignant biliary obstruction