

Supplementary Figure 1 Restricted cubic spline.

Subgroup	n (%)	No	Yes		HR (95% CI)	p	P for interaction
All patients	546 (100.00)	22/228	74/318	·	2.62 (1.57 to 4.37)	< 0.001	
Age							0.937
< 60 years	247 (45.24)	10/108	32/139	· · · · · · · ·	2.72 (1.25 to 5.94)	0.012	
≥ 60 years	299 (54.76)	12/120	42/179	· · · · · · · · · · · · · · · · · · ·	2.65 (1.30 to 5.41)	0.007	
Sex							0.339
Female	290 (53.11)	12/122	44/168		3.95 (1.94 to 8.05)	< 0.001	
Male	256 (46.89)	10/106	30/150	• • •	2.25 (0.96 to 5.27)	0.063	
History of hyperlipidemia							0.502
NO	474 (86.81)	21/205	60/269		2.64 (1.53 to 4.57)	<0.001	
YES	72 (13.19)	1/23	14/49		3860.54 (22.77 to 654631.56)	0.002	
Extrahepatic bile duct stenosis							0.897
NO	484 (88.64)	21/209	67/275	·	2.67 (1.57 to 4.53)	< 0.001	
YES	62 (11.36)	1/19	7/43		23.32 (2.77 to 196.63)	0.004	
SOD							0.909
NO	477 (87.36)	18/204	61/273		2.70 (1.53 to 4.78)	<0.001	
YES	69 (12.64)	4/24	13/45 —	<b>-</b>   ■ →	1.45 (0.26 to 7.99)	0.671	
Pancreatic duct stent							0.129
NO	256 (46.89)	4/74	45/182	·	4.71 (1.63 to 13.60)	0.004	
YES	290 (53.11)	18/154	29/136	•	1.95 (1.95 to 3.89)	0.057	
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Supplementary Figure 2 Hazard ratios and 95% confidence intervals of chyme reflux into the bile duct according to types of biliary stents in study subgroups.

Subgroup	n (%)	No	Yes				HR (95% CI)	р	P for interaction
All patients	546 (100.00)	48/228	136/318	i		<del></del>	2.48 (1.72 to 3.56)	< 0.001	
Age									0.877
< 60 years	247 (45.24)	18/108	57/139	1		·	2.89 (1.58 to 5.28)	<0.001	
≥ 60 years	299 (54.76)	30/120	79/179	1		<b>→</b>	2.59 (1.60 to 4.20)	< 0.001	
Sex				1					0.343
Female	290 (53.11)	22/122	70/168		-	•	3.37 (1.99 to 5.71)	< 0.001	
Male	256 (46.89)	26/106	66/150			_	1.88 (1.08 to 3.29)	0.026	
History of hyperlipidemia				1					0.371
NO	474 (86.81)	44/205	116/269		-		2.73 (1.86 to 4.00)	<0.001	
YES	72 (13.19)	4/23	20/49	ļ —		<b>→</b>	15.97 (1.16 to 220.36)	0.039	
Extrahepatic bile duct stenosis									0.908
NO	484 (88.64)	43/209	115/275				2.55 (1.74 to 3.75)	< 0.001	
YES	62 (11.36)	5/19	21/43	1		<b></b>	7.63 (0.94 to 61.66)	0.057	
SOD				;					0.246
NO	477 (87.36)	45/204	116/273				2.34 (1.59 to 3.44)	<0.001	
YES	69 (12.64)	3/24	20/45	-	_	<b>→</b>	16.82 (2.70 to 104.73)	0.002	
Pancreatic duct stent									0.330
NO	256 (46.89)	16/74	74/182				2.01 (1.11 to 3.64)	0.020	
YES	290 (53.11)	32/154	62/136			·	2.90 (1.80 to 4.67)	<0.001	
				0	2	4			

Supplementary Figure 3 Hazard ratios and 95% confidence intervals of CBDS according to Types of Biliary Stents in study subgroups.

Supplementary Table 1 Evaluation of postoperative safety following intro-biliary cleansing, n (%)

Variables	Total $(n = 546)$	SPBSG $(n = 228)$	DBBSG (n = 318)	P
				0.113
No	492 (90.11)	200 (87.72)	292 (91.82)	
Yes	54 (9.89)	28 (12.28)	26 (8.18)	
Nausea and vomiting				0.214
No	524 (95.97)	216 (94.74)	308 (96.86)	
Yes	22 (4.03)	12 (5.26)	10 (3.14)	
Hospitalization duration				0.039
≤1 day	232 (42.49)	105 (46.05)	127 (39.94)	
2 days	137 (25.09)	64 (28.07)	73 (22.96)	
3 days	82 (15.02)	30 (13.16)	52 (16.35)	
≥4 days	95 (17.40)	29 (12.72)	66 (20.75)	
ALT, M $(Q_1, Q_3)$	26.00 (18.00, 45.38)	26.00 (17.75, 42.25)	26.15 (18.00, 49.98)	0.278
AST, M $(Q_1, Q_3)$	28.10 (22.80, 41.88)	27.90 (22.65, 38.30)	28.45 (23.02, 44.42)	0.341
$\gamma$ -GGT, M (Q <sub>1</sub> , Q <sub>3</sub> )	32.85 (18.62, 86.25)	27.65 (16.75, 77.47)	36.85 (20.55, 98.05)	0.009
ALP, M $(Q_1, Q_3)$	79.50 (64.70, 108.93)	77.40 (63.68, 98.47)	82.65 (65.05, 115.28)	0.106
Amylase, M (Q <sub>1</sub> , Q <sub>3</sub> )	98.45 (80.10, 129.73)	98.95 (82.07, 140.35)	97.00 (77.55, 127.95)	0.166
WBC, M (Q <sub>1</sub> , Q <sub>3</sub> )	6.46 (5.15, 8.03)	6.45 (5.05, 8.29)	6.48 (5.30, 7.76)	0.854
ANC, M (Q <sub>1</sub> , Q <sub>3</sub> )	4.35 (3.18, 5.96)	4.36 (3.07, 5.95)	4.33 (3.24, 5.97)	0.747

ALT: Alanine aminotransferase; AST: Aspartate aminotransferase;  $\gamma$ -GGT:  $\gamma$ -glutamyl transpeptidase; ALP: Alkaline phosphatase; WBC: White blood cell count; ANC: Absolute neutrophil count.

## Supplementary Table 2 Sensitivity analysis of the chyme reflux into the bile duct after excluding patients with SOD

Group	Model 1		Model 2		Model 3	
	HR (95%CI)	P	HR (95%CI)	P	HR (95%CI)	P
0	1.00 (reference)	-	1.00 (reference)	-	1.00 (reference)	-
1	2.688 (1.588-4.549)	< 0.001	2.895 (1.704-4.919)	< 0.001	2.834(1.632-4.918)	< 0.001

Model 1: Model 1 was unadjusted; model 2: Model 2 was based on model 1 and additionally adjusted for age, sex, PBM and extrahepatic bile duct stricture; model 3: Model 3 was based on model 2 and further adjusted for duodenal papilla length, length of EST, DP, metal-covered biliary stents and PDS.

## Supplementary Table 3 Sensitivity analysis of the chyme reflux into the bile duct after excluding patients with Metal-covered biliary stents

Group	Model 1		Model 2		Model 3		
	HR (95%CI)	P	HR (95%CI)	P	HR (95%CI)	P	
0	1.00 (reference)	-	1.00 (reference)	-	1.00 (reference)	-	
1	2.761 (1.700-4.484)	< 0.001	2.982 (1.827-4.867)	< 0.001	2.883 (1.735-4.790)	< 0.001	

Model 1: Model 1 was unadjusted; model 2: Model 2 was based on model 1 and additionally adjusted for age, sex, PBM and extrahepatic bile duct stricture; model 3: Model 3 was based on model 2 and further adjusted for duodenal papilla length, length of EST, DP, SOD and PDS.

## Supplementary Table 4 Sensitivity analysis of the CBDS after excluding patients with SOD

Group	Model 1		Model 2		Model 3	
	HR (95%CI)	P	HR (95%CI)	$\boldsymbol{P}$	HR (95%CI)	P
0	1.00 (reference)	-	1.00 (reference)	-	1.00 (reference)	-
1	2.125 (1.501-3.008)	< 0.001	2.136 (1.506-3.031)	< 0.001	2.204 (1.514-3.208)	< 0.001

Model 1: Model 1 was unadjusted; model 2: Model 2 was based on model 1 and additionally adjusted for age, sex, PBM and extrahepatic bile duct stricture; model 3: Model 3 was based on model 2 and further adjusted for Duodenal papilla length, Length of EST, DP, Metal-covered biliary stents and PDS.

## Supplementary Table 5 Sensitivity analysis of the CBDS after excluding patients with metal-covered biliary stents

Group	Model 1		Model 2		Model 3	
	HR (95%CI)	P	HR (95%CI)	P	HR (95%CI)	$\boldsymbol{P}$
0	1.00 (reference)	-	1.00 (reference)	-	1.00 (reference)	-
1	2.280 (1.624-3.201)	< 0.001	2.257 (1.605-3.173)	< 0.001	2.361 (1.647-3.384)	< 0.001

Model 1: Model 1 was unadjusted; Model 2: Model 2 was based on model 1 and additionally adjusted for age, sex, PBM and extrahepatic bile duct stricture; Model 3: Model 3 was based on model 2 and further adjusted for duodenal papilla length, length of EST, DP, SOD Diameter of the stents and PDS.