\*

## (EndocoilTM)

= Abstract =

#### Randomised Trial of Coil (EndocoilTM Stent Versus Plastic Stent in Malignant Biliary Tract Obstruction

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Background/Aims: Endoscopic stent placement has become accepted palliative therapy for malignant biliary tract obstruction (MBTO). The main problem of plastic stent are the clogging or migration. The new self expandable super-elastic metallic coil stent (EndocoilTM Instent Inc.) is claimed to allow large lumen and prolong biliary-stent patency. In a prospective randomised trial, we compared the efficacy and frequency of stent dysfunction of Endocoil Mand plastic stent (Percuflex R Microvasive Co.). Method: Between Aug. 1994 and Mar. 1995, we assigned 29 patients (21 males and 8 females, mean age 63 years) with unresectable MBTO due to cancer of bile duct (17), pancreas (6) periampullary (3), gallbladder (2) and perichoedochal LN (1). Thirteen of patients underwent EndocoilTM stents (24 Fr) and other 16 patients underwent plastic stents (12 Fr) insertion via transpapillary route. Successful insertion of stents was attained all cases and no serious complication occured. Results: All patients with EndocoilTM stents and 11 (68%) patients with plastic stents were relieved completely from jaundice (T. bilirubon < 3.0mg/dl). There was no differences in decreasement of bilirubin between two groups after 7 days and 30 days after stents insertion. Median patency of the stents was significantly prolonged in patients with EndocoilTM stents compared with those with plastic stents

		,		1998 7	: 120-752,	, Tel: 361-5422, Fax: 365-2125
		1995	11	39		
*	1					

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(205 days vs 92 days). The stent dysfunction was noted 2 cases (15%) in EndocoilTM due to tumor ingrowth. In contrast, stent dysfunction was occured in 10 cases (62%) of plastic stents due to clogging (7 cases) and migration (3 cases). The patients' overall median survival was not different significantly between two groups (EndocoilTM250 days vs plastic 196 days). **Conclusions:** Both EndocoilTM and plastic stents offer effective bile drainage in MBTO. However EndocoilTM stents may be more effective for providing longer periods of drainage due to lower frequency of stent dysfuction than plastic stents. **(Korean J Gastrointest Endosc 19: 235 241, 1999)** 



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 Table 1. Clinical Charateristics of the Patients

	Endocoil (n=13)	Plastic (n=16)	p value
Age (mean, years)	62	66	NS
Sex (M/F)	10/3	11/5	NS
Diagnosis			
Bile duct cancer	7	10	
Pancreas cancer	3	3	
Periampullary cancer	2	1	
Gallbladder cancer	_	2	
Pericholedochal LN	1	_	
Initial TB (mg/dL)*	15.5 7.1	17.6 + 8.8	NS

\*Mean ± SD; NS, not significant statistically; LN, lymph node; TB, total bilirubin

#### (Table 1).

2)	
(1) EndocoilTM	: E

- (1) EndocoilTM : EndocoilTM (Instent Co.) (delivery catheter) ,
- .

# . 12 Fr

(releasing handle) , 24 Fr . 24

2

Fr 7 5 cm, 6 cm, 7 cm , 8 1 . EndocoilTM (ERCP) (EST) Soehendra dilator 12 Fr

gui-

가 .

Xguidewire . (2) : ERCP EST

12 Fr Amsterdam polyethylene (PercuflexR Microvasive Co.) X-

. (3) : EndocoilTM , 7,30 7

3 mg/dL 7 7 30 (4) 7 2 1 24 ,

ERCP

, , , , (5) : t-test ,

chi-square test . 1996 8 30 Kaplan-Meier Log-Rank test .



Table	2.	Efficacy	for	Relief	of	Jaundice
1 ante	4.	Efficacy	101	Rener	01	Jaunuice

	Endocoil (n=13)	Plastic (n=16)	p value
Relief of jaundice (TB < 3.0 mg/dL)	13 (100%)	11 (68%)	0.24
Bilirubin decrease (m	ng/dL)*		
7 days after	$9.0 \pm 3.0$	8.7 ± 5.1	0.85
insertion			
30 days after	$13.9 \pm 7.3$	11.7 ± 6.9	0.45
insertion			

\*Mean ± SD; TB, total bilirubin

Table	3.	Causes	of	Stent	Dysfunction
I unit	•••	Cuubeb	01	Dienie	Dystanetion

Causes	Endocoil (n=13)	Plastic (n=16)	p value
Stent dysfuction	2 (15%)	10 (62%)	0.07
Blockage	-	5	
Migration	-	2	
Tumor ingrowth	2	_	
Days of stent patency*	$205 \pm 82$	$92 \pm 44$	0.003

\*Mean ± SD; Follow up duration : 1 13 months

(p=0.09). 7 30 ( ) 9.0, 13.9 mg/dL , 8.7, 11.7 mg/dL

(Table 2).

### 2)

- 13 2 (15%) EndocoilTM
- 16 10 (62%) , clogging 7 , migration 3
- 7} (p=0.07)(Table 3). 205
  - 92 (p < 0.05)(Fig. 1).
- 3)
  - 13 6 , 4
    - , 7



Fig. 1. Cummulative patency of EndocoilR and plastic stents.

	5 :	(Endocoil <b>TM)</b>	239
	10 , 5	CoilTM stent)	
6		가 ,	
250	, 196		
			가 가
ERBD)	(endoscopic retrograde biliary drainage,	.2)	가 가
EKDD)	가	29	
	,16)	12 Fr (68%) 기 3.0 mg	, 16 11 13 /dI
	.7-9)	7 - 7 - 7	30
	teflon, polyethylene stent, Gianturco-Rosch Z stent, Strecker	30 50%	3 5 (clogging)
	(clogging) .7-9)	,279) フト フト 8 Fr	7} , Speer 8) 10 Fr
ble)	가 (self expanda- (wire)	10, 12, 15 Fr 가 Fr polyethylene	. 12 16 10 (62%) , 7
가 가	7 <del>)</del> 18	92 .	2) 12 Fr 143 .
	, 가 가 .10-16) stent (Endo-	, , Goldin 19) 1	9

	日におり代現学首応・分1	91254725619999			
12					
	5	2			가
2,4		, 4.5	,		
	4				
				,	가
	3) 5				
		1			
1					가
	4	6			
•		13			
	3.0 n	ng/dL			
		,			
	,				1994
	2		8	1995 5	
		가 .			
		205	29	(13)	(16 )
	92				
			1)		7 ), (6
				(3), (2)	
		, Smits		) 21	8
20) 28				63 (36 80 )	가
	20 71%		•		
	8 3	, 5	2)	18 mm	
				12 Fr	Amsterdam
	2				
,	2 2		2)		
1	ERCP		3) 2.0. mg/dI		
debris7⊦	irrigation		3.0 mg/dL	11 (68%) 3.0	ma/dI
	3)		10	11 (08%) 5.0	liig/dL
•				7	30
	•				
			4)	13 2 (15%)	
			1 /	10 (20)	
	가		16	5 10 (62%)	
	۲r		_		

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가 (p=0.07).

clogging 7 , migration 3



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