

(Endocoil™)

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= Abstract =

Randomised Trial of Coil (Endocoil™ 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 (Endocoil™ 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™ and plastic stent (PercuflexR, 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) perampullary (3), gallbladder (2) and perichoedochal LN (1). Thirteen of patients underwent Endocoil™ 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 occurred. **Results:** All patients with Endocoil™ stents and 11 (68%) patients with plastic stents were relieved completely from jaundice (T. bilirubon <3.0 mg/dl). There was no differences in decrease 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 Endocoil™ stents compared with those with plastic stents

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Table 1. Clinical Characteristics 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) Endocoil™ : Endocoil™
 (Instent Co.)
 (delivery catheter)
 ,
 .
 12 Fr
 (releasing handle)
 ,
 24 Fr .
 Fr 가 5 cm, 6 cm, 7 cm 24
 , 8 1 2 30
 Endocoil™
 (ERCP)

Soehendra dilator
 de-wire
 X-
 guidewire
(2) :
 ERCP EST
 12 Fr Amsterdam
 polyethylene (PercuflexR Microvasive Co.)
 X-
(3) : Endocoil™
 , 7 , 30 가
 3 mg/dL 가
 7 30
(4) 가: 1
 2 1 24 ,
 ERCP
 , ,
(5) :
 t-test ,
 chi-square test . 1996 8
 Kaplan-Meier Log-Rank
 test .

1) ERCP irrigation debris가
 2) Endocoil™
 3) migration
 4) clogging
 5) debris가

(p=0.09).
 7 30
 ()
 9.0, 13.9 mg/dL ,
 8.7, 11.7 mg/dL
 (Table 2).
 2) 13 2 (15%)
 Endocoil™
 16 10 (62%)
 , clogging 7
 , migration 3
 가 (p=0.07)(Table 3).
 205

Table 2. Efficacy for Relief of Jaundice

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

*Mean ± SD; TB, total bilirubin

Table 3. Causes of Stent Dysfunction

Causes	Endocoil (n=13)	Plastic (n=16)	p value
Stent dysfunction	2 (15%)	10 (62%)	0.07
Blockage	—	5	
Migration	—	2	
Tumor ingrowth	2	—	
Days of stent patency*	205 ± 82	92 ± 44	0.003

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

92
 (p < 0.05)(Fig. 1).
 3) 13 6 , 4
 , 7



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

Coil™ stent)

10 , 5

6 가 ,

250 , 196

가 가

가 가

(endoscopic retrograde biliary drainage, .2)

ERBD)

가 29

,16) 12 Fr 16 11

(68%) 13

가 3.0 mg/dL

.79) 가

7 30

teflon, polyethylene

Wall stent, Gianturco-Rosch Z stent, Strecker

stent

3 5

30 50% (clogging)

가

(clogging) ,279)

.79) 가 , Speer 8) 10 Fr

가 8 Fr

가 가 (self expandable) (wire)

10, 12, 15 Fr

Fr 가 12

polyethylene 16 10 (62%)

, 7

가 가 가 92 . 2) 12 Fr

18 143

33%

.10-16) , Goldin 19) 9

Instent (Endo-

1

12
 2 , 4 5 2 가
 , 4.5 , 가
 4 , 가
 . 3) 5 1 가
 1 4 6 . 가
 . 13
 3.0 mg/dL
 , 1994
 2 8 1995 5
 가 .
 205 29 (13) (16)
 92 .
 1) (17) , (6)
) , (3) , (2)
 , Smits (1) 21 8 가
 2) 63 (36 80) 가
 20 71%
 8 3 , 5 2) 18 mm
 12 Fr Amsterdam
 , 2 .
 1 2 3)
 ERCP 3.0 mg/dL
 debris가 irrigation 16 11 (68%) 3.0 mg/dL
 3) . 7 30
 4) 13 2 (15%)
 16 10 (62%)
 가 가 (p=0.07).

