

Helicobacter pylori Omeprazole

Comparison of the Different Products of Omeprazole based Triple Therapy for *Helicobacter pylori*-Positive Peptic Ulcer Disease

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Background/Aims: We prospectively compared the efficacy and safety of the two products of omeprazole based triple therapy in patients with *Helicobacter pylori* (*H. pylori*)-positive active peptic ulcer. **Methods:** Seventy-four patients with endoscopically proven active peptic ulcer were divided into two groups: OAC-I group (n=37) which received the 6-weeks treatment of A product of omeprazole (20 mg, b.i.d.) plus 2 weeks treatment of amoxicillin (500 mg, b.i.d.) and clarithromycin (500 mg, b.i.d.); OAC-II group (n=37) which received 6 weeks treatment of B product of omeprazole (20 mg, b.i.d.) plus 2 weeks treatment of the same antibiotics. The *H. pylori* and ulcer healing status were assessed at baseline and at the end of the 6-week therapy. Gastrointestinal symptoms, adverse events were checked and the standard laboratory examination was performed at each visit. **Results:** Eradication of *H. pylori* [intention to treat (n=77)/per protocol (n=66)] and healing rate of ulcer were 83.8%/ 96.9% and 93.8% in OAC-I group, 91.9%/100% and 97.1% in OAC-II group (P=0.477, P=0.608). No significant differences were found in symptom resolution, adverse events, and laboratory monitoring between the two groups. **Conclusions:** The two different products of omeprazole based triple therapy for ulcer showed similar healing rates and safety after 6-weeks treatment in patients with *H. pylori*-positive active peptic ulcer. (**Kor J Gastroenterol 2000;36:29 - 38**)

Key Words: Products of omeprazole, Peptic ulcer disease, *Helicobacter pylori*

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H. pylori 1983 Warren Marshall

H. pylori vs. B) *H.*

pylori

H. pylori

.2

36

.7 NIH consensus *H.*

pylori *H.*

pylori .89

H. pylori 1.

1999 1 1999 10

proton pump (PPI) 0.5 cm *H. pylori*

benzimidazole hydrogen/ 가 74

potassium adenosine triphosphatase (H⁺, K⁺-ATPase) 4

.9 , H2 ,

PPI PPI

.10

PPI 가 Helsinki 가

가 가

2

2.

1 가 가

.11-14 0.5

cm CLO ,

H. pylori , *H. pylori* *H. pylori*

.15-17 *H. pylori* 74

OAC- (n=37) OAC- (n=37)

OAC- 6

A (20 mg, b.i.d.,) 2

(500 mg, b.i.d.)

(500 mg, b.i.d) OAC- 6

H. pylori B (20 mg, b.i.d.,

) 2 (500 mg, b.i.d.)

H. pylori (500 mg, b.i.d)

(A 3

가 SAS(Release 6.12) .

10 가 6 P 0.05

CLO (hema-
toxylin eosin , Warthin-Starry
) *H. pylori* .

1.

가 CLO 74 47 (19-75)
H. pylori 2.1:1 가
H. pylori 가

2

4 가 18 , 19
CLO , *H. pylori* OAC-I 9.5 ± 3.9
가 *H. pylori* cm, OAC-II 8.1 ± 3.5 cm OAC-I
(Table 1).
74 (intention to
treat) 8 (10.8%)
4 (0; , 1; , 2; 3;
)
OAC-II 2) 2 가가
protocol 2
(OAC-I 1 , OAC-II 1)
가
2 2
1
2
가 .
3.
± ,
chi-square test Fisher's exact test
Student's t-test .

2.

가 Intention-to-treat (n=74) *H.*
log-rank test *pylori* OAC-I 83.8%, OAC-II
91.9% per protocol (n=66) *H.*
pylori OAC-I 96.9%, OAC-II
100% (Table 2,
(intra-group comparison) P=0.477). OAC-I OAC-II
(inter-group compari-
son). *H. pylori* protocol 93.8% 97.1%
가 per protocol (Table 2, P=0.608). OAC-II OAC-I
가 (88.2%
intention-to-treat vs. 100%) .

Table 1. Baseline Demographic and Ulcer Characteristics of Patients

	OAC-	OAC-	p-value
	n=37 (%)	n=37 (%)	
Mean Age (years)	45.9 ± 12.6*	49.0 ± 12.8*	0.292
Sex (male:female)	25:12	25:12	0.999
Previous ulcer (yes:no)	19:18	17:20	0.642
Smoker (yes:no)	18:15	20:14	0.724
Ulcer size (mm)	9.5 ± 3.9*	8.1 ± 3.5*	0.074 †
Stomach	18	18	0.228
10 mm	12 (32.4)	16 (43.2)	
>10 mm	6 (16.2)	2 (5.4)	
Duodenum	19	19	0.999
10 mm	16 (43.2)	17 (45.9)	
>10 mm	3 (8.1)	2 (5.4)	

* mean ± standard deviation

† analyzed by Wilcoxon's rank sum test

Table 2. Results of the Eradication Study

	OAC- (%)	OAC- (%)	p-value
<i>H. pylori</i> eradication			0.477
PP	31/32 (96.9%)	34/34 (100%)	
ITT	31/37 (83.8%)	34/37 (91.9%)	
Ulcers healed	30/32 (93.8%)	33/34 (97.1%)	0.608
Stomach	15/17 (88.2%)	15/15 (100%)	
Duodenum	15/15 (100%)	18/19 (94.7%)	
Ulcers healed	32/32 (100%)	34/34 (100%)	0.848
A H (stage)	2/32 (6.3%)	1/34 (2.9%)	
A S (stage)	30/32 (93.8%)	33/34 (97.1%)	
Adverse events	4/32	1/34	0.358
Skin rash	1	0	
Diarrhea	1	0	
Taste disturbance	1	0	
Epigastric pain	1	1	
Study discontinued	5/37	3/37	0.711
Protocol violation	3	2	
Poor cooperation	1	1	
Adverse events	1	0	
Study continued	32/37	34/37	

PP, per protocol; ITT, intention-to-treat.

(95.5%)

OAC-I

9.5 ± 3.9 cm

0.2 ± 0.6 cm

OAC-II

8.1 ± 3.5 cm

0.2 ± 0.9

(P=0.001, P=0.001).
 가 , , , 3.
 가 (Table 3). Log 6 2
 rank test
 OAC-I 1
 OAC-II (Fig. 1). 4
 가

Table 3. Effects of Treatment on the Symptom-days between Two Groups*

Symptoms	OAC- (days)	OAC- (days)	p-value
Ulcer pain	5.3 ± 2.8	6.8 ± 5.5	0.388
Dyspepsia	7.4 ± 3.8	6.5 ± 4.1	0.575
Anorexia	8.0 ± 5.6	9.0 ± 8.5	0.880
Nausea	4.6 ± 3.4	9.7 ± 14.4	0.388
Vomiting	3.0 ± 0.0	5.0 ± 4.2	0.766

* mean ± standard deviation.

Table 4. The Results of Laboratory Monitoring in Both Groups*

	OAC- (n=37)			OAC- (n=37)			p-value †
	-1 week	6 week	p-value	-1 week	6 week	p-value	
Hemogram							
Hemoglobin (g/dL)	13.9 ± 20	14.1 ± 1.2	0.348	13.9 ± 1.6	13.8 ± 1.3	0.868	0.155
WBC (10 ³ /μL)	7.2 ± 22	6.4 ± 2.2	0.038	7.2 ± 2.3	6.1 ± 1.9	0.013	0.784
Platelet (10 ³ /dL)	253.4 ± 60.9	240.9 ± 48.9	0.099	250.7 ± 62.0	243.4 ± 53.6	0.069	0.901
Blood chemistry							
Albumin (g/L)	4.8 ± 0.3	4.8 ± 0.3	0.923	4.8 ± 0.4	4.7 ± 0.4	0.138	0.301
Creatinine (mg/dL)	1.0 ± 0.2	1.0 ± 0.2	0.130	1.1 ± 0.4	1.0 ± 0.3	0.213	0.791
T-Bil (mg/dL)	0.78 ± 0.49	0.71 ± 0.26	0.307	0.7 ± 0.3	0.8 ± 0.4	0.135	0.144
AST (U/L)	27.2 ± 27.5	29.9 ± 25.7	0.620	24.8 ± 9.4	30.1 ± 25.8	0.196	0.567
ALT (U/L)	29.2 ± 34.5	30.7 ± 27.6	0.857	28.2 ± 13.2	32.7 ± 24.9	0.271	0.606
ALP (U/L)	75.7 ± 19.4	81.7 ± 20.3	0.061	82.0 ± 20.7	86.9 ± 29.0	0.041	0.830
Uric Acid (mg/dL)	5.2 ± 1.0	4.6 ± 1.0	0.033	5.1 ± 1.5	4.7 ± 1.3	0.216	0.312
T-Chol (mg/dL)	192.3 ± 41.9	200.7 ± 40.5	0.128	194.7 ± 33.9	194.1 ± 44.2	0.932	0.082
Glucose (mg/dL)	99.8 ± 21.1	100.1 ± 12.7	0.854	104.7 ± 33.9	110.7 ± 30.5	0.263	0.078
Urinalysis							
pH	6.3 ± 0.9	6.5 ± 1.1	0.385	6.4 ± 1.0	6.3 ± 1.0	0.767	0.481

* mean ± standard deviation

† t-test for the changes of values before and after the treatment in both groups; WBC, white blood cell; T-bil., total-bilirubin; AST, aspartate aminotransferase; ALT, alanine aminotransferase; ALP, alkaline phosphatase; T-Chol, total-cholesterol.

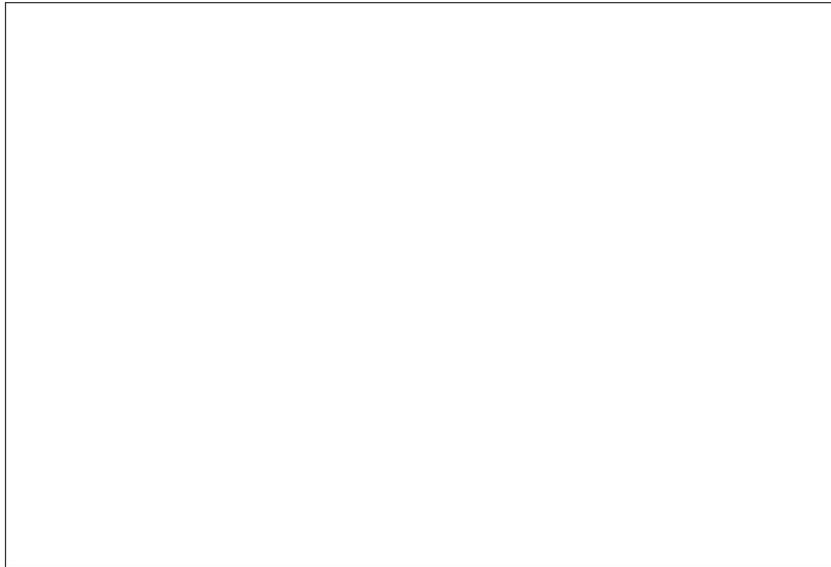


Fig. 1. The survival analysis (log rank test) of symptom-days. OAC- group tended to have longer ulcer pain than OAC- group, but no significant statistical difference was found between two groups.

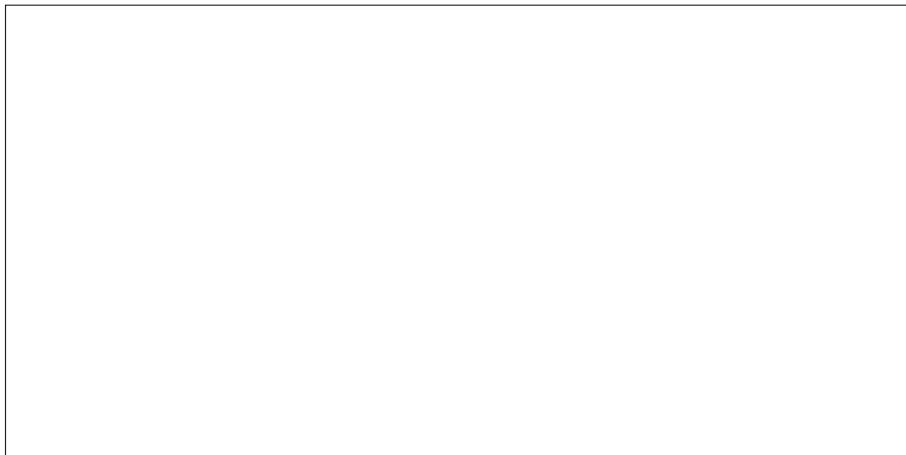


Fig. 2. Comparison of two different products of omeprazole. Two different products of omeprazole have their own alkalinizing agents in the core component and enteric-coated outer substances in order to be protected from gastric acid. HPMC, Hydroxypropylmethyl cellulose; HPMCAS, Hydroxypropylmethyl cellulose acetate succinate; HPMCP, Hydroxypropylmethylcellulose phthalate.

(Table 2).

(Table 4).

OAC-I uric acid OAC-II
alkaline phosphatase 가가

Bismuth

H. pylori

10%
 .1819 pH
 1520 PPI .10
 가 (,
 metronidazole/tinidazole) 가
H. pylori .28
 1 .1314 pH (A vs. B)
 PPI 가
 가 21
 . A (tablet)
H. pylori (Fig. 2)
 . In vitro *H. pylori* hydroxypropyl methylcellulose acetate succinate
 (HPMCAS)
 가 가 .22 L-arginine
 가 가
 2324 PPI B (capsule)
 sodium hydrophosphate (NaHPO4)
H. pylori
 hydroxypropyl methylcellulose acetate succinate
 (HPMC) hydroxypropyl methylcellu-
 lose acetate phthalate (HPMCP)
 78-95% .2527 (Table 5). HPMCAS HPMCP
H. pylori 가 .28
 , 가 6 *H.*
pylori
 (P=0.477, P=0.608)
 가
H. pylori
 가 OAC
 가
H. pylori
 H+/K+-ATPase 가
 PPI
 2
 . 2 *H. pylori*
 가
 가 .
 American Digestive Health Foundation *H. pylori*

Conference 2 .29 0.5

cm *H. pylori*

가 *H. pylori* 74 OAC- (n=37) OAC- (n=37)

가 331 OAC- 6 A (20 mg, b.i.d.) 2

가 32 (500 mg, b.i.d.) (500 mg, b.i.d.) OAC-

2 6 B (20 mg, b.i.d.) 2

가 4 . 가

H. pylori . 2

4 (0; , 1; , 2; 3;)

가 . : Intension to

OAC-I uric treat 77 *H. pylori*

acid , OAC-II alkaline phosphatase OAC- 83.8%, OAC- 91.9%

가 (intra-group analysis) per protocol 66 *H. pylori*

OAC- 96.9%, OAC- 100%

OAC- 93.8% 97.1%

H. pylori

가

H. pylori . :

H. pylori

H. pylori

_____ *H. pylori*

: , , *H. pylori* : , , *Helico-*

bacter pylori

H. pylori

H. pylori

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H. pylori

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