

1~2 기 본태성 고혈압 환자들에서 Imidapril 대 Enalapril의 항고혈압 효과를 평가하기 위한 무작위, 이중맹검 임상시험

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A Randomized, Double-Blind Clinical Trial to Determine the Efficacy of Imidapril vs. Enalapril in Patients with Stage 1 to 2 Essential Hypertension

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ABSTRACT

Background : Imidapril is a long-acting angiotensin converting enzyme inhibitor, which has been demonstrated to be effective in reducing blood pressure. The purpose of this study is to compare the antihypertensive efficacy, safety and tolerability of imidapril and enalapril in patients with stage 1 to 2 essential hypertension. **Methods** : In this double-blind, double-dummy, randomized, parallel study, the efficacy, safety and tolerability of once-daily imidapril versus once-daily enalapril were evaluated in 84 patients with stage 1 - 2 hypertension during 8 weeks. If antihypertensive response was insufficient after 4 week treatment period, the dosage for both study drugs doubled until the end of study. **Results** : Data from 84 patients who completed the study were eligible for per-protocol analysis. An adequate antihypertensive effect was observed in 47.6% (20/42) in the imidapril group and in 23.8% (10/42) in enalapril group. There was statistically significant difference between the two treatments in the percentage of patients achieving a "reduced blood pressure". The pulse rate did not changed in both groups. Safety profiles were similar between treatments. **Conclusion** : In patients with mild to moderate hypertension, the imidapril group showed better response with regard to antihypertensive effect. Both imidapril and enalapril were well tolerated with similar safety profiles. (**Korean Circulation J 1999;29(11):1234-1239**)

KEY WORDS : Hypertension · Imidapril.

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서 론

Angiotensin Converting Enzyme inhibitor(ACEI) 1, 2 (JNC V) 5 (90 mmHg) , 2 3 ,

¹⁾²⁾³⁾

가 방 법

⁴⁾ Imidapril(Tanatril,) Tanabe ACEI imidapril enalapril
 ACEI diacid imidaprilat 4 , peak
 prodrug . Imidaprilat 90mmHg
 ACE inhibitory activity enalapril en- (5 8)
 alaprilat 2 , captopril 10 가 . peak 90 mmHg
⁵⁾ imidapril 10 mg 1 1 1 1 5 mg 1 10 mg , en-
 ACE 85 90% .⁶⁾ Imidapril alapril 1 1 5 mg
 ACEI 가 0.9 3.7% 1 10 mg 가 .
 1 2 imida-
 pril enalapril 1 1 , 가
 (-2 , 0 , 4 , 8)

대상 및 방법

계 획 10 12 8
 4 가 1 1 imidapril(5 mg, 5 2
 enalapril(5 mg, 10 mg) 2
 , 가 8 , 가 5 mmHg 가
 , , ,
 1 2 1
 (wash - out period) 2
 (placebo period, 2 , , ,
 가) , , , ,

대상환자의 선정

4 8 ,

가 . 가 .
 가 , 가
 , 가
 자료의 통계적 처리
 Chi - Square
 t
 , Fisher
 (Table 1),
 8
 Chi - Square
 Fisher
 p 0.05
 SAS Version 6.11

결 과

imidapril 63
 enalapril 49 , imidapril 42
 enalapril 42 75%
 21 7 ,
 가 (Table 2).

Table 1. Criteria for evaluation of changes (mmHg) in systolic (SBP), diastolic (DBP) and mean blood pressure (MBP)

	Reduced	Slightly reduced	No change	Increased
SBP	20	10 - 19	9	10
DBP	10	5 - 9	4	5
MBP	13	7 - 12	6	7

Efficacy

가 Table 1
 8
 imidapril
 47.6%(20/42) , enalapril 23.8%(10/42)
 imidapril (Ta-
 ble 3).
 imidapril 76.2%(32/42) , en-
 alapril 52.4%(22/42)
 . Fig. 1 0 8
 (1 5 mg) imidapril
 100%(6/6) , enalapril 33.4%(2/6) ,
 (1 10 mg) imidapril 38.6%
 (14/36) , enalapril 22.2%(8/36)
 (Table 3).

Safety

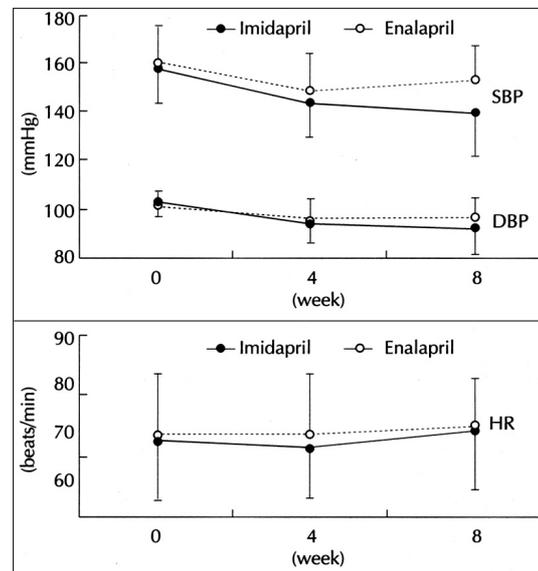


Fig. 1. Changes in blood pressure and heart rate during the study. Blood pressure decreased significantly compared with baseline in both treatment groups (p<0.05, paired t-test).

가 imidapril 4.8%(2), enalapril 7.1%(3) .

perprotocol analysis imidapril 9(21.4%) enalapril 11(26.2.0%) (Table 4).

가 ACEI 8)9)

가

Table 2. Demographic characteristics

	Imidapril group	Enalapril group
Sex (M/F)	16/26	22/20
Age (years)	52 ± 8.7	56 ± 8.9
Bwt (kg)	65 ± 7.9	65 ± 10.3
Hypertension severity		
Mild	14	16
Moderate	28	26
SBP (mmHg)	156 ± 12.4	159 ± 14.2
DBP (mmHg)	102 ± 5.5	101 ± 4.9
HR (beats/min)	73 ± 8.3	74 ± 10.1

Mean ± SD, Hypertension severity was graded according to The JNC V, All parameters were measured at the end of the Observation period, No significant differences were found Between groups

Table 3. Evaluation of changes in blood pressure

	Reduced	Slightly reduced	No change	Increased	Total	Overall response				
						Reduced (%)	POR	95% CI	p value	
Imidapril group	20	12	10	0	42	47.6	2.91	1.04 - 8.26	0.04*	
Enalapril group	10					23.8				
									0.06**	
5 mg										
Imidapril group	6	0	0	0	6	100	-	-	NS*	
Enalapril group	2	3	1	0	6	33.4				
10 mg										
Imidapril group	14	12	10	0	36	38.8	2.23	0.71 - 7.13	NS*	
Enalapril group	8	9	16	3	36	22.2				
Mild										
Imidapril group	6	4	4	0	14	42.9	3.25	0.50 - 23.4	NS**	
Enalapril group	3	4	7	2	16	15.0				
Moderate										
Imidapril group	14	8	6	0	28	50.0	2.71	0.76 - 10.0	NS*	
Enalapril group	7	8	10	1	26	26.9				

POR : prevalence odds ratio CI : confidence interval * : ² test

** : Fisher's exact test

Table 4. Frequency of clinical adverse effects

	Imidapril (n = 42)	Enalapril (n = 42)
	2	3
	1	1
	1	0
	0	1
	2	1
	1	0
	1	0
	1	0
	2	3
Total	11 (26%)	9 (21%)

Angiotensin II receptor (ATIIR) blocker
 Angiotensin II receptor (ATIIR) blocker, ACEI, bradykinin
 prostaglandin

가 . ACEI imidapril
 enalapril . Imidapril Ta-
 nabe ACEI ,
 imidapril 47.
 6% , enalapril 23.8%
 Saruta ¹¹⁾ 71.3%, 66.1%

Saruta 12
 . Imidapril
 imida-
 prilat가 enalapril
 2 , captopril 10
 ACE inhibitory activity ⁵⁾

가
 enalapril
 가
 (1 5mg)
 가 enalapril 33.4%(2/6
) imidapril 100%(6/6)
 , RAS activation

imidapril
 ACE inhibitory action
 가 .
 가
 . Saruta ¹¹⁾ 0.9%
 imidapril ACEI
 , imidapril 4.8%(2) ,
 enalapril 7.1%(3)
 7.8% Yoo imidapril
¹³⁾
 Renin - angiotensin system

ATIIR1 blocker ACEI
 Angiotensin
 ATIIR1 blocker가
 Park ¹⁴⁾
 ATIIR1 blocker 4.3%

ATIIR1 blocker ACEI
 Angiotensin
 ATIIR1 blocker가
 Park ¹⁴⁾
 ATIIR1 blocker 4.3%

RAS ATIIR1 blo-
 cker가 ACEI
 가 imidapril
 ACEI
 ATIIR blocker RAS가
 ACEI potency가
 가

요 약
 연구배경 :
 1 2 imida-
 pril enalapril 1 1 ,

방 법 :
 , 1 1 imidapril(5 mg, 4

가 10 mg) enalapril(5 mg,
 10 mg) 1 2
 84 , 가
 가 .
 결 과 :
 8 imidapril 47.6%
 (20/42), enalapril 23.8%(10/42) imida-
 pril .
 imidapril 76.2%(32/42), enalapril 52.4%
 (22/42) .
 결 론 :
 1 1 imid-
 april enalapril
 , imidapril
 enalapril .
 중심 단어 : . Imidapril · Enalapril.

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