A Comparison of Four Primary Classes of Antihypertensive Monotherapy in Thai Patients

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Abstract

Efficacy of four primary classes of antihypertensive agents (diuretics, angiotensin converting enzyme inhibitors, calcium antagonists, adrenergic inhibiting drugs) were compared by using a crossectional medical record survey between July 1997 and January 1998. Only hypertensive cases with initial monotherapy were studied. The evaluations were 1) blood pressure response after drug titration and 2) blood pressure response during the maintenance phase. Two hundred and eighty nine patients were studied. After dose titration, the mean reduction in systolic blood pressure with calcium antagonists (33±24 mmHg, mean ± SD) was better than other drugs ($p<0.05$) while there was no difference in the other three drug classes in systolic blood pressure reduction.The mean reduction in diastolic blood pressure with calcium antagonists (17±9 mmHg) was better than angiotensin converting enzyme inhibitors (13 ± 9, $p = 0.02$) but without significant difference compared to the other two drug classes There was no difference in diastolic blood pressure reduction from diuretics, angiotensin converting enzyme inhibitors and adrenergic inhibiting drugs. In the maintenance phase, the response rate for calcium antagonists (82.6%) was better than angiotensin converting enzyme inhibitors (54.2%, $p = 0.004$) but was not better than the other two drug classes. Response rates for diuretics, angiotensin converting enzyme inhibitors and adrenergic inhibiting drugs were not statistically different.

Key word : Hypertension, Drug Efficacy

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Initial drug therapy for mild-to-moderately-severe hypertension was recommended by the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC) in their 1997 report[1] to be monotherapy, i.e. starting with a single drug. Both the 1997 and 1993 JNC Reports [2] recommended a diuretic or a beta blocker as the initial choices in uncomplicated cases because

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numerous randomized controlled trials had shown a reduction in morbidity and mortality with these agents. In general, antihypertensive efficacy may vary little between the various available drugs[3] but there was a lot of evidence suggesting differential racial responses[4-8]. In a randomized, double-blind study, angiotensin-converting enzyme (ACE) inhibitor (ACEi) was found to be the least effective in black patients while there were no significant differences in the response rates of white patients to various antihypertensive drugs[9]. Although there was some evidence suggesting that Thai hypertensive patients may be less responsive to ACE inhibitor in comparison with a calcium antagonist[10], the possibility of significant difference in response to various antihypertensive drugs in Thai people is far from conclusive.

We studied four different classes of antihypertensive drugs used as monotherapy for patients with mild-to-severe hypertension in the outpatient clinics of Maharaj Nakorn Chiang Mai Hospital. Our primary objective was to assess the comparative efficacy of each drug class in lowering blood pressure in a Thai hypertensive population.

MATERIAL AND METHOD

Study design and patient selection

A crossectional medical record survey of hypertensive and isolated systolic hypertension of outpatients who attended the cardiology clinic or general medical clinic of Maharaj Nakorn Chiang Mai Hospital from July 1997 to January 1998 was carried out. Nine hundred and twenty four hypertensive patients who visited these two clinics during that time interval and all of their outpatient cards were reviewed. Case-inclusion criteria were 1) adult non-pregnant patients with pre-treatment systolic blood pressure between 140 and 200 mmHg or pre-treatment diastolic blood pressure between 90 and 114 mmHg 2) all had to have their initial antihypertensive drug as monotherapy from one of the following four primary classes (diuretics, ACE inhibitors, calcium antagonists or adrenergic inhibiting drugs) 3) all had to have good and regular follow-up records at least in the first few visits during which antihypertensive drug titration was made so that the initial therapeutic response could be evaluated. Case-exclusion criteria were 1) those who had been treated with more than one antihypertensive agent from the beginning. 2) those whose hypertension was diagnosed and treated before their initial visits. 3) patients with renal insufficiency (creatinine level $\geq$ 2.5 milligrams/dl), atrial fibrillation, secondary hypertension or congestive heart failure. Blood pressures were measured after 5-minute rest and recorded by registered nurses, nurse-assistants or physicians and the fifth Karotkoff sounds were used for diastolic blood pressure. If more than one blood pressure measurement had been made in each hospital visit, the average values were used for calculation. Considering antihypertensive drug therapy for blood pressure as low as 140/90 mmHg was justified for patients within the high-risk category[12] so these levels were used as our lower threshold levels for patient inclusion.

Evaluation of blood-pressure response after dose titration

Averaged pretreatment blood pressure recordings from visits when physicians initiated antihypertensive monotherapy were used as pretreatment controls. Averaged blood pressure from visits after final monotherapy dose-adjustments were used for response evaluation. Criteria for response were 139 mmHg or less for systolic blood pressure and 89 mmHg or less for diastolic blood pressure. These criteria were used because they were considered as normal blood pressure in every recent guideline including the sixth report of the JNC[1] and the 1999 WHO-ISH Guidelines[12] The dosage of antihypertensive drugs used after final titration were recorded and catagorized as low, medium and high dose, these dosage definitions are listed in Table 1. We used the mean usual dose for adults suggested in our latest Hospital Formulary as the criteria for medium dosage definition[11]. The possible side effects from each antihypertensive drug mentioned in the outpatient cards were reviewed from the time that they had been started until 6 months or 1 year of follow-up.

Evaluation of blood-pressure response during the maintenance phase

Blood pressure recordings from patients who continued the initial antihypertensive monotherapy for 1 year or 6 months were used for evaluation. The 6-month data were used if the treatment was changed or withdrawn between 6 months or 1 year after initiation. Definition of blood-pressure responses during the maintenance phase was an average diastolic blood pressure of 89 mmHg or less both at the end of titration phase and at the end

Table 1. Antihypertensive drugs used as monotherapy and their dosages in each definition.

Drugs	Dose difinition (milligrams/day)		
	Low	Medium	High
Diruetics			
Hydrochlorothiazide	12.5	25	50
Indapamide	-	2.5	-
ACE inhibitors			
Enalapril	5-10	20	Above 20
Perindopril	2-4	8	Above 8
Ramipril	2.5	5	Above 5
Cilazapril	2.5	5	Above 5
Quinapril	5-10	20	Above 20
Lisinopril	5-10	20	Above 20
Calcium antagonists			
Nifedipine	10-30	40	Above 40
Amlodipine	5	10	Above 10
Felodipine	5	10	Above 10
Nicardipine	30	60	Above 60
Nitrendipine	5	10	Above 10
Isradipine	2.5	5	Above 5
Verapamil	80	160	240
Adrenergic inhibiting drugs			
Beta-adrenergic receptor blockers			
Atenolol	25-50	100	Above 100
Bisoprolol	2.5	5	Above 5
Propranolol	40-80	120-160	Above 160
Metoprolol	50	100	Above 100
Pindolol	5	10	15
Alpha-adrenergic receptor blockers			
Doxazosin	2	4	Above 4
Prazosin	2-4	5-10	Above 10

of 6 months or 1 year of monotherapy. If patients had isolated systolic hypertension (pretreatment diastolic blood pressure readings of 89 mmHg or less)(12), response was defined as a systolic blood pressure of 139 mmHg or less both at the end of titration and at the end of 6 months or 1 year of monotherapy.

Statistical analysis

The effectiveness of each primary class of antihypertensive therapy was assessed by the following comparisons

1. The efficacy of each drug class to reduce systolic blood pressure.
2. The efficacy of each drug class to reduce diastolic blood pressure.
3. The rate of diastolic blood pressure response after titration.
4. The rate of systolic blood pressure response after titration.
5. The rate of blood pressure response in the maintenance phase.

Diastolic blood pressure evaluations were performed only in those patients with abnormal baseline diastolic blood pressure. The efficacies of each drug class were compared by using student *t* test. The rate of blood pressure responses after titration and in the maintenance phase were compared by using Fisher's exact test and Yate's chi-square test. The differences between the groups were considered significant at $p < 0.05$.

RESULTS

Characteristics of patients

Among 924 outpatient cards reviewed, 289 patients (168 females and 121 males) fitted our inclusion criteria and were selected for analysis. The number of cases in each treatment group depended on the physician's drug preference. Diuretics in 112 cases, ACE inhibitors were used in 69 cases, calcium antagonists in 65 cases and adrenergic inhibiting drugs in 43 cases. We also divided the patients into younger (those less than 60 years old) and older (those 60 years old or older) and eva-

luated their blood pressure responses to each antihypertensive class. The mean (± SD) age of the 169 younger patients was 48 ± 8 years and was 66 ± 5 years for the 120 older patients. There were 35 patients (12%) with isolated systolic hypertension (pretreatment diastolic blood pressure were less than 90 mmHg[12]), mean pretreatment systolic pressure was 171.3 mmHg, most of them (26 patients) were in the older age group. The mean systolic blood pressure (± SD) and diastolic blood pressure (± SD) in the younger patient group were 165 ± 16 mmHg and 103±6 mmHg while they were 172 ± 17 mmHg and 99 ± 9 mmHg respectively in the older patient group. Base line characteristics of included patients were shown to be well balanced across the four treatment groups (Table 2).

High total cholesterol levels (serum cholesterol above 200 mg/dl) were found in 142 subjects from 187 subjects on whom the blood test was performed (75.9%), within this group very high total cholesterol (serum cholesterol above 240 mg/dl) was found in 78 subjects (41.7%). There were 26 cases (9%) with diabetes mellitus, 33 cases (11.4%) with a history of coronary heart diseases (angina or myocardial infarction), 13 cases (4.5%) with a history of stroke (ischemic or hemorrhagic) or transient ischemic attacks. Left ventricular hypertrophy (evidenced from any of the following investigations, chest roengentnography, electrocardiography, echocardiography) were found in 53 patients from 193 who was investigated (27.5%). Evidence for albuminuria (urinalysis results) was found in 65 from 127 patients (51%).

Of the 289 records used for evaluation, 56 did not qualify for the evaluation for blood pressure response in the maintenance phase because there had been changes in the treatment or the duration of treatment had not been long enough. Thus, 233 subjects 80.6%) were evaluated for response in the maintenance phase.

Blood pressure response after dose titration

The mean reduction of systolic and diastolic blood pressure after diuretics, ACE inhibitors, calcium antagonists and adrenergic inhibiting drugs dose titration is shown in Table 3. The pairwise comparisons indicated that the mean reduction in systolic blood pressure was significantly greater with calcium antagonists than with all the other drugs (p=0.01 compared with diuretics, p=0.02

Table 2. Baseline characteristics of all patients and patients in each treatment group.

Characteristics	All patients	D	ACEi	CA	AID
Number of patients (%)	289 (100)	112 (39)	69 (24)	65 (22)	43 (15)
Age (mean ± SD, years)	56 ± 11	56 ± 11	57 ± 11	56 ± 11	53 ± 11
Systolic BP (mean ± SD, mmHg)	168 ± 17	165 ± 13	170 ± 16	175 ± 22	166 ± 15
Diastolic BP (mean ± SD, mmHg)	101 ± 8	103 ± 5	104 ± 5	104 ± 5	104 ± 5
Pulse rate (mean ± SD, beats/minute)	82 ± 13	81 ± 12	82 ± 11	83 ± 10	81 ± 13
Body weight (mean ± SD, kilograms)	61 ± 11	60 ± 11	61 ± 11	63 ± 12	61 ± 10

BP denotes blood pressure, D diuretics, ACEi angiotensin converting enzyme inhibitors, CA calcium antagonists, AID adrenergic inhibiting drugs.

Table 3. Average blood pressure reduction from baseline at the end of titration.

	D	ACEi	CA	AID
Systolic BP (mean ± SD, mmHg)	26 ± 18	24 ± 21	33 ± 24*	23 ± 17
Diastolic BP (mean ± SD, mmHg)	15 ± 10	13 ± 9	17 ± 9**	14 ± 11

D denotes diuretics, ACEi angiotensin converting enzyme inhibitors, CA calcium antagonists, AID adrenergic inhibiting drugs

* significantly better than all other groups ($p < 0.05$)

** significantly better than ACEi ($p = 0.02$)

with ACE inhibitors, p=0.01 compared with adrenergic inhibiting drugs). For diastolic blood pressure, the mean reduction with calcium antagonists was better than ACE inhibitors (p=0.02) but had no significant differences from the other two treatment groups.

The proportion of patients reaching the response criteria for diastolic blood pressure with calcium antagonists was significantly higher than with ACE inhibitors (88.7% *vs* 68.4%, p=0.012) (Fig. 1A) but without statistically significant differences from other monotherapy. The diastolic blood pressure response rates for diuretics, ACE inhibitors and adrenergic inhibiting drugs were not different statistically. The proportion of patients reaching the systolic blood pressure goal were the same in every treatment group (Fig. 1B). The only difference between the younger patient group and the older was that the proportion of younger patients reaching diastolic blood pressure goal in the calcium antagonists group was significantly higher than ACE inhibitors (88.9% *vs* 63.9%, p=0.026) but there was no significant difference between calcium antagonists and ACE inhibitors in the older group (88.5% *vs* 76.2%, p=0.437) (Table 4).

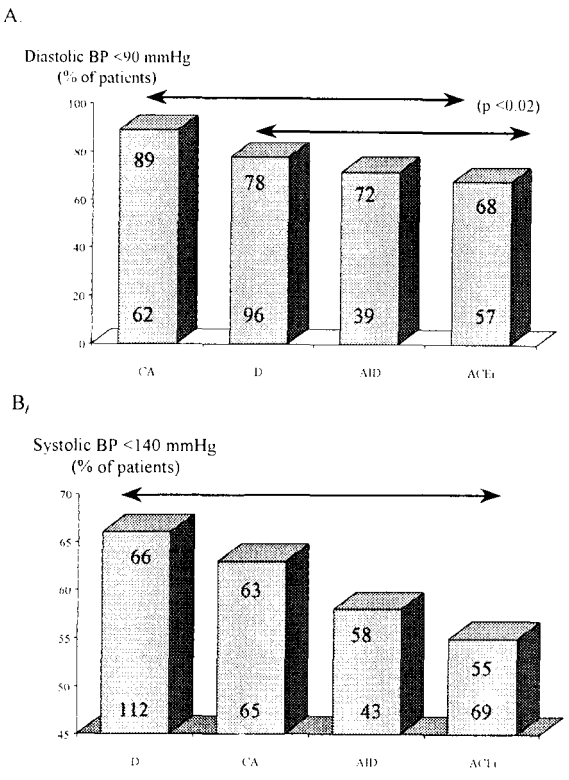

Fig. 1. Patients with a diastolic blood pressure of less than 90 mmHg or a systolic blood pressure of less than 140 mmHg at the end of titration.

D denotes diuretics, CA calcium antagonists, ACEi angiotensin converting enzyme inhibitors, AID adrenergic inhibiting drugs. The numbers at the top of the bars indicate the percentage of patients with the response shown, and the numbers at the bottom of the bars indicate the number of patients in each group. On the basis of pair wise comparison, the horizontal arrows group drugs the effect of which were not significantly different from one another, but were significantly different from the drugs not included under the arrow.

The dosage profiles after drug titration showed that medium to low dosage was used in 50 per cent of diuretics, 95 per cent of angiotensin converting enzyme inhibitors, 97 per cent of calcium antagonists and 88 per cent of adrenergic inhibiting drugs. Patients in the diuretic group had the highest proportion of using high dose therapy (50%) because most of them had been started with the daily dose of 50 milligrams hydrochlorothiazide which was considered as high dose (Table 1) in this study.

Blood pressure response during the maintenance phase

Of the 233 patients evaluable in the maintenance phase, 90 were in the diuretics group (80.0% of patients with diuretics), 59 in the angiotensin converting enzyme inhibitors group (85.6%), 46 in the calcium antagonists group (70.7%) and 38 in the adrenergic inhibiting drugs group (88.4% of patients with adrenergic inhibitors). The proportion of patients with blood pressure response in each of the treatment groups is shown in Fig. 2. The rate of response reflected the combination of the initial blood-pressure responses, the number of patients who did not withdraw and the degree to which control was maintained. The pairwise comparisons showed that calcium antagonists were more effective than angiotensin converting enzyme inhibitors (p=0.004) but were no different from the others. Angiotensin converting enzyme inhibitors were as effective as diuretics (p=0.074) and adrenergic inhibiting drugs (p=0.510) When age was considered, younger patients had better response with calcium antagonists (83.3%) than with angiotensin converting enzyme inhibitors (53.3%) (p=0.04), while the older patients showed no differences in response to each of the four types of monotherapy. However, there was a trend toward better response (p=0.09) for the older patients with calcium antagonists

Table 4. Percentage of patients who reached the response criteria for systolic and diastolic blood pressure at the end of titration and percentage of patients who responded in the maintainance evaluation.

	Younger				Older				All			
	D	ACEi	CA	AID	D	ACEi	CA	AID	D	ACEi	CA	AID
Titration sBP response	60.9	52.6	63.9	61.3	72.9	58.1	62.1	50.0	66.1	55.1	63.1	58.1
Titration dBP response	71.2	63.9	88.9*	68.9	89.2	76.2	88.5	80.0	78.1	68.4	88.7**	71.8
Maintenance response	62.8	53.3	83.3*	65.5	79.5	55.2	81.8	55.6	70.0	54.2	82.6**	63.2

* better than ACEi in the younger age group ($p = 0.026$ for titration evaluation, $p = 0.04$ for maintenance evaluation)
** better than ACEi in the whole group ($p = 0.012$ for titration evaluation, $p = 0.004$ for maintenance evaluation)

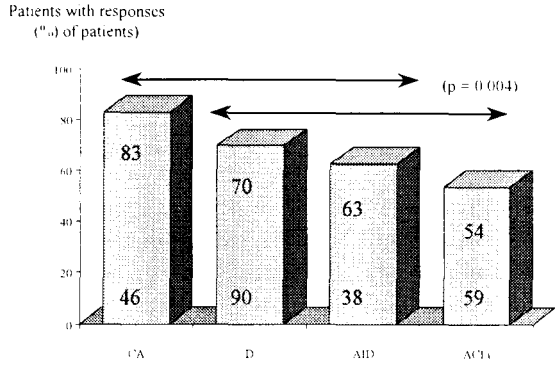

Fig. 2. Patients with responses in each of the treatment groups. The abbreviations and arrows are explained in the legend of Fig. 1.

(81.8% response) than the older patients with angiotensin converting enzyme inhibitors (55.2%) (Table 4).

Rates of treatment success were different for the different drugs in younger and older patients (Table 4). Younger patients responded best to calcium antagonists, adrenergic inhibiting drugs, diuretics, angiotensin converting enzyme inhibitors; and older patients to calcium antagonists, diuretics, adrenergic inhibiting drugs, angiotensin converting enzyme inhibitors (listed in descending order).

Adverse drug effects

All possible adverse drug effects recorded in the outpatient cards after drug titration for 6 months or 1 year were used for evaluation. There were 16 patients (9.5%) in the younger age group and 11 patients (9.2%) in the older age group who complained about possible adverse drug effects. Fifteen who were treated with angiotensin converting enzyme inhibitors (21.7%) had adverse experiences and eleven required drug discontinuation, almost all suffered from cough of varying severity only one had palpitation and one had skin rashes. Eight patients (12.3%) from the calcium antagonists group had adverse drug effects described as headache, dizziness, palpitations, hot flushing, and edema, none of them needed drug modifications. Only three patients from the diuretic group (2.7%) had adverse drug effects namely fatigue, rashes and hypokalemia. One patient (2.3%) had pulmonary wheezes while being treated with a beta blocker.

DISCUSSION

An important limitation for this study was that it was neither randomised nor double blind. One most important finding was that angiotensin-converting enzyme inhibitors may be less effective in a Thai population especially when compared with a calcium antagonist (Fig. 1A, Table 4, Fig. 2). This finding confirms the previous observation which suggested that nifedipine had better efficacy in blood pressure reduction than cilazapril in Thai patients[10]. The problem that always limits good interpretation of a non-randomised trial is the study-group differences. In our study, although there was a difference in the number of patients being treated by each drug class we were very fortunate to have nearly identical baseline characteristics of patients with angiotensin converting enzyme inhibitors and

patients with calcium antagonists (Table 2) and the percentage of patients who required high-dose regimens in both groups was also nearly identical (5% and 3% respectively) which means that it can be properly compared. The reading bias in blood pressure measurements is an important confounding factor in every blood pressure study, we believe that although this kind of error may unavoidably existed in our study it should be equally distributed among each study group so it should not have a very significant effect on the results. Also the criteria for assessment of drug efficacy were pre-defined and the investigators played no role in blood pressure measurement of any case so investigator bias should be minimal although the design was not double blinded.

In most comparative studies for antihypertensive drug efficacy assessments, only one drug from each major antihypertensive class was used (3,4,6,8-10). In our study, various drugs from each class were evaluated together as one group, this method was not unreasonable because in fact, efficacy varies little between the various available drugs that belong to the same group(13) and this kind of class evaluation was reported recently(14).

The mechanisms underlying the different responses among the classes of agents in a certain population remain unclear. It has been proposed that blacks and the elderly may be less responsive to angiotensin-converting enzyme inhibitors and more responsive to diuretics and calcium antagonists because they tend to have low plasma renin activity(15,16). Another reason that may explain the poorer efficacy of angiotensin-converting enzyme inhibitors in our study is the nature of high-sodium food in most northern parts of Thailand which can cause low circulating renin levels in this patient group. Our results also suggested that Thai patients may be more responsive to diuretics than to angiotensin-converting enzyme inhibitors (Fig. 1A, 1B, 2) although this was not statistically proved. This finding could support low plasma r enin hypothesis in the Thai hypertensive population.

The question of whether the patient's age could be a determinant of the response to some antihypertensive drugs has often been mentioned. Diuretics and calcium antagonists have been reported by other authors to be more effective in elderly patients(17,18). Our findings also suggested better responses for elderly patients treated with diuretics but there seemed to be no influence of age on calcium angatonist responses (Table 4).

It should also be noted that our studied hypertensive population had a very high percentage of abnormal cholesterol levels (75.9% above 200 mg/dl, 41.7% above 240 mg/dl) which could not be explained by cases with diabetes (9%). The significance of this finding, however, should be further investigated in a future more properly designed trial.

Although angiogensin-converting enzyme inhibitors seemed to have a higher incidence of adverse events and withdrawal than the other treatment groups, these may be overestimated because there were no placebo controls in our study. The incidence of cough from ACEi in the Thai hypertensive population was reported to be 12 per cent (19). Because our patients were selected group with very good compliance by strict inclusion criteria and because we could not estimate the true withdrawal incidence from this crosssectional survey design, we could have over or underestimated the side effects from each treatment group and they should not be compared with each other.

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การศึกษาเปรียบเทียบประสิทธิภาพของยาลดความดันโลหิต 4 กลุ่มหลักในผู้ป่วยไทย

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ได้ทำการศึกษาเปรียบเทียบประสิทธิภาพของยาลดความดันโลหิตกลุ่มหลัก 4 กลุ่มคือ ยาขับปัสสาวะ, ยาต้าน angiotensin converting enzyme, ยาต้านแคลเซียมและยาต้านระบบประสาทซิมพาเทติค โดยใช้วิธีการศึกษาจากบันทึกรายงานผู้ป่วยนอกที่มาตรวจระหว่างเดือนกรกฎาคมปี พ.ศ. 2541 ถึงเดือนมกราคมปี พ.ศ. 2542 ผู้วิจัยได้คัดเฉพาะผู้ป่วยที่มีความดันโลหิตก่อนรักษาอยู่ในระดับสูงน้อยถึงสูงมากและได้เริ่มการรักษาด้วยยาลดความดันโลหิตเพียงชนิดเดียว โดยดูที่การตอบสนองขั้นแรกหลังปรับขนาดยาและดูการตอบสนองระยะยาว จากผู้ป่วยที่ศึกษาจำนวน 289 รายพบว่า เมื่อปรับขนาดยาแล้ว ยาต้านแคลเซียมสามารถลดความดันซีสโตลิคได้ดีกว่ายาอื่น (33 $\pm$ 24 มมปรอท, mean $\pm$ SD) ($p<0.05$) ส่วนประสิทธิภาพในการลดความดันซีสโตลิคของยาอีก 3 กลุ่มที่เหลือไม่มีความแตกต่างกัน และยาต้านแคลเซียมสามารถลดความดันไดแอสโตลิคได้ดีกว่ายาต้าน angiotensin converting enzyme (17 $\pm$ 9 เทียบกับ 13 $\pm$ 9 มมปรอท, $p=0.02$) แต่ไม่ได้มีประสิทธิภาพดีกว่ายาอีก 2 กลุ่มที่เหลือ และประสิทธิภาพในการลดความดันไดแอสโตลิคในยา 3 กลุ่มคือยาขับปัสสาวะ ยาต้าน angiotensin converting enzyme และต้านระบบประสาทซิมพาเทติคพบว่าไม่มีความแตกต่างกัน ส่วนการตอบสนองระยะยาวพบว่ายาต้านแคลเซียมมีประสิทธิภาพดีกว่ายาต้าน angiotensin converting enzyme (ตอบสนองร้อยละ 82.6 เทียบกับร้อยละ 54.2, $p = 0.004$) แต่ไม่ได้มีประสิทธิภาพดีกว่ายาอีก 2 กลุ่มที่เหลือและประสิทธิภาพในการตอบสนองระยะยาวของยา 3 กลุ่มคือยาขับปัสสาวะ ยาต้าน angiotensin converting enzyme และยาต้านระบบประสาทซิมพาเทติคไม่มีความแตกต่างกัน

คำสำคัญ : ประสิทธิภาพของยาลดความดันโลหิต, ความดันโลหิตสูง

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