

Long-Term Efficacy of Olmesartan Medoxomil in Chinese Hypertensive Patients as Assessed by Clinic, Ambulatory and Home Blood Pressure Measurements

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Abstract

Background and Objectives There is limited information on the long-term efficacy and safety of olmesartan medoxomil in the management of hypertension in Chinese patients. We therefore conducted the present multicentre, single-arm, prospective, observational study to investigate the 24-week efficacy and safety of olmesartan medoxomil in patients with mild to moderate hypertension.

Methods Eligible patients (diastolic blood pressure [BP] 90–109 mmHg and systolic BP <180 mmHg off antihypertensive medication) were started on olmesartan medoxomil 20 mg once daily, with the possible up-titration

to 40 mg once daily during 24 weeks of follow-up, to control clinic BP to the target level (<140/90 and <130/80 mmHg in diabetes mellitus). In a subset of enrolled patients, 24-h ambulatory and home BP monitoring were also performed.

Results In the intent-to-treat analysis ($n = 348$), at 24 weeks of follow-up, the mean \pm SD changes from baseline in clinic systolic/diastolic BP were $21.2 \pm 14.2/16.0 \pm 8.8$ mmHg ($p < 0.001$). The proportions of patients who achieved the goal BP for systolic, diastolic and both were 81, 80 and 75 %, respectively. Olmesartan medoxomil also significantly ($p < 0.001$) reduced systolic/diastolic BP measured at patients' homes by $17.7 \pm 13.1/12.1 \pm 7.9$ mmHg from baseline ($n = 109$), and reduced mean 24-h, daytime and night-time ambulatory BP by $13.3 \pm 16.3/7.6 \pm 9.5$ mmHg, $13.9 \pm 17.4/8.0 \pm 10.4$ mmHg and $12.3 \pm 18.1/6.8 \pm 10.2$ mmHg, respectively ($n = 87$). Seven (2.0 %) serious adverse events were reported during follow-up.

Conclusion In Chinese hypertensive patients, olmesartan medoxomil is efficacious in lowering BP as assessed by three different BP-measuring methods and has an acceptable long-term safety and tolerability profile.

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1 Introduction

Olmesartan medoxomil is one of the most recently developed angiotensin II type 1 receptor antagonists (angiotensin receptor blockers [ARBs]), and has been available in the Chinese market for a few years [1]. Previous studies in American [2] and European populations [3] have demonstrated that olmesartan medoxomil is more efficacious in reducing blood pressure (BP) than other ARBs at equivalent dosages. Indeed, in a multicentre, randomized, double-blind, 8-week, comparative trial of four ARBs, the mean

reduction in clinic diastolic BP (DBP) from baseline was significantly greater with olmesartan medoxomil 20 mg daily (11.5 mmHg) than with losartan 50 mg daily (8.2 mmHg), valsartan 80 mg daily (7.9 mmHg) and irbesartan 150 mg daily (9.9 mmHg) [2]. Similar findings were observed in the same study for clinic systolic BP (SBP) [2] and for ambulatory BP [4], and in a meta-analysis of 36 studies that compared various ARBs with each other or with other classes of antihypertensive drugs or placebo [5].

However, there is still very limited information on the long-term efficacy and safety of olmesartan medoxomil in the management of hypertension in Chinese patients. We therefore conducted the present multicentre, single-arm, prospective, observational study to investigate the 24-week efficacy and safety of olmesartan medoxomil 20–40 mg once daily in treating mild to moderate hypertension in Chinese patients.

2 Methods

2.1 Study Design

This multicentre, open-label, single-arm, prospective study was conducted in the outpatient clinic of 16 tertiary hospitals in China. The study protocol was approved by the Ethics Committee of Zhongshan Hospital, Fudan University, Shanghai, China, and as appropriate also by the Ethics Committees of the participating hospitals. All subjects gave written informed consent.

2.2 Patients

Patients eligible for inclusion in the present study had to be aged 18–75 years, and have a baseline clinic DBP of 90–109 mmHg and a clinic SBP below 180 mmHg, after being off antihypertensive medication for at least 1 week. Clinic BP was an average of six readings taken at two run-in clinic visits, at which BP was measured on the right arm three times consecutively by use of a standard mercury sphygmomanometer. Exclusion criteria were secondary hypertension, isolated systolic hypertension (clinic SBP ≥ 140 mmHg and clinic DBP < 90 mmHg), obesity (body mass index ≥ 30 kg/m² or body weight ≥ 100 kg), use of β -blockers or agents that would influence BP, pregnancy or childbearing potential, severe liver (serum alanine transaminase ≥ 2 times the upper limit of the normal range) and renal (serum creatinine ≥ 1.5 times of the upper limit of the normal range or proteinuria $\geq 2+$ on a dipstick test) function impairment, indications for using other drugs that may affect the BP of patients, hypersensitivity to the study drug,

and other conditions that the investigator thought inappropriate for study enrolment.

2.3 Treatment and Follow-Up

All enrolled subjects were treated initially with olmesartan medoxomil 20 mg once daily, with the possible up-titration to 40 mg once daily at 4, 8, 12, 16 and 20 weeks of follow-up, to achieve the goal of clinic SBP/DBP control to a level of $\leq 130/80$ mmHg in diabetes mellitus or $\leq 140/90$ mmHg in the absence of diabetes. Other antihypertensive drugs could be added if clinic BP exceeded 180 mmHg SBP or 110 mmHg DBP. Olmesartan medoxomil was supplied free by Daiichi Sankyo Pharmaceutical (Shanghai) Co., Ltd for the whole study period, and as instructed was taken in the early morning hours after getting up.

Clinic BP was measured on the right arm three times consecutively by the investigators using a standard mercury sphygmomanometer immediately before olmesartan medoxomil was taken. BP was also measured in a similar fashion at the subjects' home for 7 consecutive days before each of the clinic visits using an automated electronic BP monitor (HEM-4021, Omron, Kyoto, Japan). In all subjects from five of the 16 participating hospitals that consented, ambulatory BP monitoring was performed at baseline and at 24 weeks of follow-up using a validated BP monitor (SpaceLabs 90207 and 90217, SpaceLabs Healthcare, Issaquah, WA, USA). On the day of ambulatory BP monitoring, olmesartan medoxomil was taken after ambulatory BP monitoring was started.

2.4 Efficacy and Safety Evaluations

Efficacy was primarily evaluated as the changes from baseline in clinic SBP and DBP measured immediately before the study drug was taken at 24 weeks of follow-up. The secondary efficacy variables included clinic BP changes from baseline to 4, 8, 12, 16 and 20 weeks of follow-up, the proportion of patients who attained the goal clinic BP and, as appropriate, the BP changes from baseline for ambulatory and home monitoring during follow-up.

All adverse events reported by patients or observed by investigators at any time during the trial were recorded on a case report form and assessed for seriousness and relationship to the study drug. The results of all laboratory tests were also assessed by investigators for clinical significance and for possible relationship to the study drug.

2.5 Statistical Methods

For efficacy, we performed an intent-to-treat analysis in patients who complied with all the required criteria for inclusion and who started treatment with olmesartan

medoxomil and had at least one follow-up visit; a per-protocol analysis was performed in patients who completed the 24-week follow-up. Categorical and continuous variables were analysed by the Chi-squared (χ^2) test and analysis of variance (ANOVA), respectively. The changes in BP from baseline to various follow-up visits were analysed with the paired *t* test. The safety analysis included all enrolled patients who had started treatment with olmesartan medoxomil. Adverse event data were analysed by Fisher's exact test. A *p* value ≤ 0.05 was considered statistically significant.

3 Results

3.1 Characteristics of Patients

Of the 360 patients enrolled in the present study, 357 had started treatment with olmesartan medoxomil and were therefore included in the safety analysis. Of these 357 patients, nine were excluded from intent-to-treat analysis because they did not fully comply with all the study requirements as defined in the study protocol. Of these 348 patients, 46 were further excluded from the per-protocol analysis because they were lost to follow-up (*n* = 7), had added other antihypertensive drugs for uncontrolled BP (*n* = 20) or because they withdrew from the study medication for adverse events (*n* = 12) or other reasons (*n* = 7). Thus, the intent-to-treat and per-protocol analyses included 348 and 302 patients, respectively (Fig. 1).

The 357 patients in the safety analysis comprised 164 women (45.9 %) and 25 (7.0 %) patients with diabetes at baseline. Mean \pm SD values at baseline were 52.2 ± 9.0 years of age, 24.9 ± 2.8 kg/m² for body mass index and 149.0 ± 11.0 mmHg/ 97.2 ± 5.0 mmHg for clinic SBP/DBP (Table 1).

During follow-up, of the 348 patients in the intent-to-treat analysis, 177 (50.9 %) remained on olmesartan medoxomil 20 mg throughout the 24 weeks of follow-up, 135 (38.8 %) up-titrated to 40 mg daily at 4–20 weeks of

Table 1 Patient characteristics at baseline (*n* = 357)

Characteristic	Men (<i>n</i> = 193)	Women (<i>n</i> = 164)	<i>p</i> Value
Age (years)	51.2 \pm 9.6	54.0 \pm 8.4	0.005
Body mass index (kg/m ²)	25.4 \pm 2.6	24.7 \pm 3.1	0.02
Blood pressure (mmHg)			
Clinic systolic	147.8 \pm 12.0	150.3 \pm 10.9	0.05
Clinic diastolic	97.6 \pm 5.1	96.8 \pm 4.9	0.16
Heart rate (beats/min)	74.0 \pm 9.1	73.9 \pm 8.6	0.93
Diabetes mellitus	13 (6.7 %)	12 (7.3 %)	0.76

Values are mean \pm SD except for diabetes mellitus (*n* [%]), which was defined as a fasting plasma glucose concentration of at least 7.1 mmol/L or the use of antidiabetic drugs

follow-up, and 36 (10.3 %) stopped olmesartan medoxomil with or without the addition of other antihypertensive drugs.

3.2 Blood Pressure Reductions on Clinic Measurements

In the intent-to-treat analysis (*n* = 348), at 24 weeks of follow-up or the last follow-up visit, the mean \pm SD changes in clinic SBP/DBP from baseline were $21.2 \pm 14.2/16.0 \pm 8.8$ mmHg (*p* < 0.001, Fig. 2), and the proportions of patients who achieved the BP target for SBP, DBP and both were 81, 80 and 75 %, respectively (Fig. 3). At 4, 8, 12, 16 and 20 weeks of follow-up, the mean \pm SD changes from baseline in SBP/DBP were $15.3 \pm 14.2/11.8 \pm 9.0$ mmHg, $19.0 \pm 14.1/14.7 \pm 8.8$ mmHg, $20.1 \pm 13.8/15.3 \pm 8.4$ mmHg, $21.1 \pm 14.5/15.7 \pm 9.0$ mmHg and $21.5 \pm 14.4/16.2 \pm 8.8$ mmHg, respectively (*p* < 0.001, Fig. 2).

Similar findings were observed in the per-protocol analysis (*n* = 302), with slightly higher proportions of patients who achieved the goal BP for SBP (82 %), DBP (82 %) and both (77 %) at 24 weeks of follow-up (Figs. 2 and 3).

3.3 Home and Ambulatory Blood Pressure Monitoring

In 109 patients, BP was measured at the subjects' home. The mean \pm SD changes from baseline in SBP/DBP were $11.4 \pm 12.5/8.9 \pm 7.7$ mmHg, $13.9 \pm 11.8/9.9 \pm 7.7$ mmHg, $15.5 \pm 12.1/10.6 \pm 8.0$ mmHg, $16.1 \pm 12.1/11.3 \pm 7.8$ mmHg, $17.6 \pm 12.7/12.1 \pm 7.8$ mmHg and $17.7 \pm 13.1/12.1 \pm 7.9$ mmHg at 4, 8, 12, 16, 20 and 24 weeks of follow-up, respectively (*p* < 0.001).

In 87 patients, ambulatory BP monitoring was performed. The mean \pm SD changes from baseline to 24 weeks of follow-up were $13.3 \pm 16.3/7.6 \pm 9.5$ mmHg,

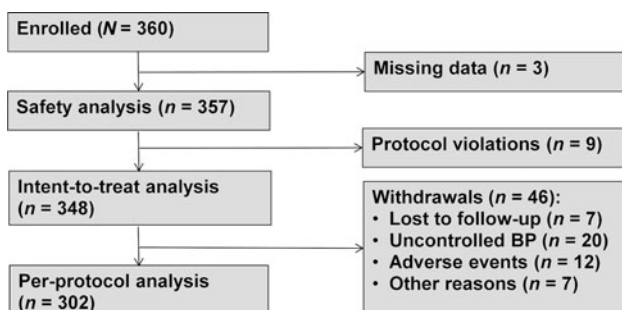
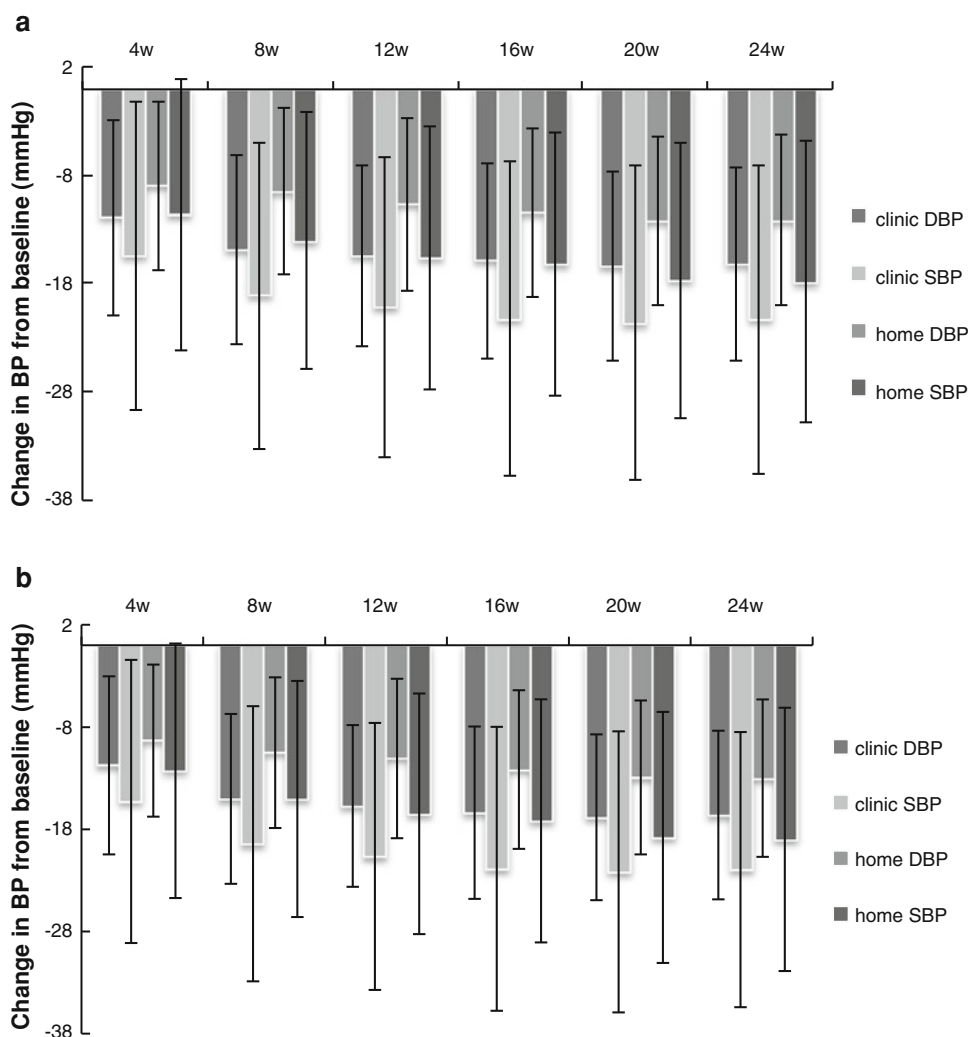


Fig. 1 Patient flow chart. BP blood pressure

Fig. 2 Mean \pm SD changes from baseline in clinic and home SBP and DBP at 4, 8, 12, 16, 20 and 24 weeks of follow-up in (a) the intent-to-treat ($n = 348$) and (b) the per-protocol ($n = 302$) analyses. The differences between baseline and follow-up values were statistically significant for all follow-up visits ($p < 0.001$). BP blood pressure; DBP diastolic BP; SBP systolic BP



$13.9 \pm 17.4/8.0 \pm 10.4$ mmHg and $12.3 \pm 18.1/6.8 \pm 10.2$ mmHg for 24-h, daytime and night-time SBP/DBP, respectively ($p < 0.001$).

3.4 Safety and Tolerability

Of the 357 patients who had ever taken olmesartan medoxomil during follow-up, 80 (22.4 %) reported at least one episode of adverse event, including seven (2.0 %) patients with a serious adverse event (one for each of the following seven events: haemorrhagic stroke, myocardial infarction, unstable angina pectoris, glomerular nephritis, elevated serum concentration of alanine transaminase, dizziness and lumbar disc herniation) and 33 (9.2 %) patients with an adverse event that was considered by the investigator to be related to the use of the study drug (including one serious adverse event). The incidence rates of dizziness, upper respiratory tract infection, headache, asthenia, visual disturbance, flatulence and elevation of

serum alanine transaminase exceeded 1 % of the enrolled study participants (Table 2).

4 Discussion

Our study demonstrated similar BP reductions from baseline to several comparative studies that had a washout run-in phase and compared olmesartan medoxomil with placebo [6, 7], other ARBs [1–3, 8, 9] or other classes of antihypertensive drugs [6, 7] in American [2, 6, 7], Chinese [1, 8] and European populations [3, 9].

In a multicentre, randomized, double-blind trial in patients with diastolic hypertension (a clinic DBP of 100–115 mmHg and a mean daytime ambulatory DBP of 90–120 mmHg), the reductions in clinic SBP/DBP from baseline were $-11.3/-11.5$ mmHg after 8 weeks of treatment with olmesartan medoxomil 20 mg daily [2]. The corresponding values in mean daytime ambulatory blood

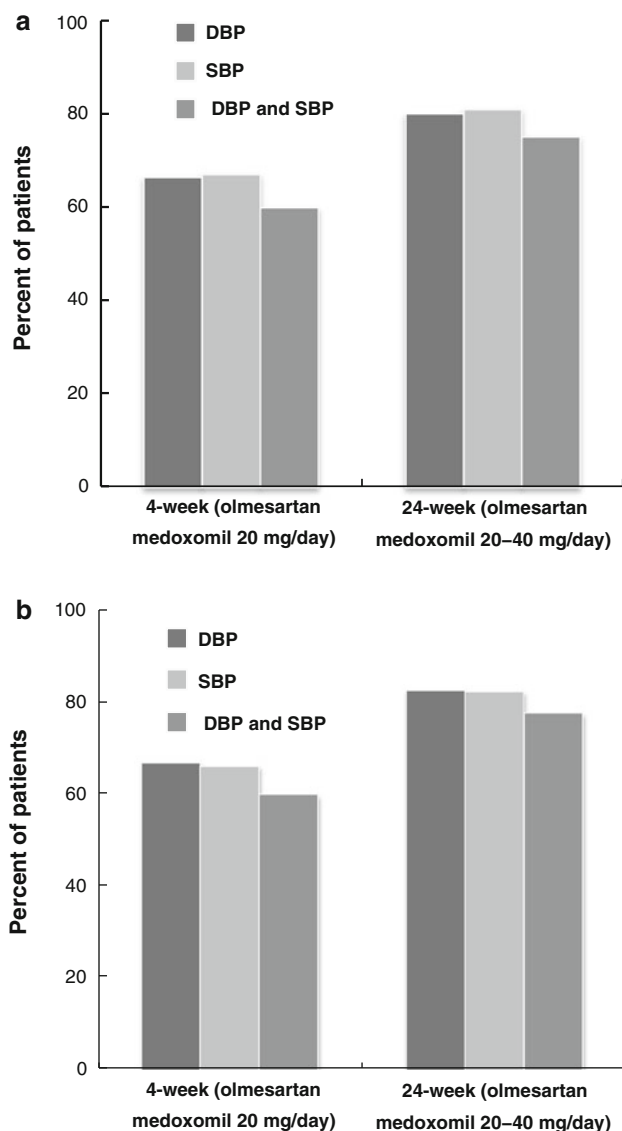


Fig. 3 Proportion of patients who attained the goal blood pressure for SBP (<130 mmHg in patients with diabetes mellitus or <140 mmHg in the absence of diabetes), DBP (<80 mmHg or <90 mmHg, respectively), and both SBP and DBP at 4 weeks (olmesartan medoxomil 20 mg/day) and 24 weeks (olmesartan medoxomil 20–40 mg/day) of follow-up in (a) the intent-to-treat ($n = 348$) and (b) the per-protocol ($n = 302$) analyses. *DBP* diastolic blood pressure; *SBP* systolic blood pressure

pressure were $-12.5/-8.5$ mmHg [2]. In an 8-week, randomized, double-blind, parallel-group study, the mean changes from baseline to 8 weeks of follow-up in the olmesartan medoxomil (20 mg daily) group were $-21.2/-15.8$ mmHg for clinic SBP/DBP and $-13.0/-9.3$ mmHg for mean daytime ambulatory DBP [3]. In a 12-week, randomized, double-blind, forced-titration study, the mean changes from baseline to 8 weeks of follow-up in the olmesartan medoxomil (40 mg once daily) group were $-13.9/-11.7$ mmHg for clinic SBP/DBP [4]. In a meta-

Table 2 Adverse events in the safety analysis ($n = 357$ patients)

Adverse event	No. of patients	Incidence rate (%)
Dizziness	22	6.2
Upper respiratory tract infection	10	2.8
Headache	9	2.5
Asthenia	5	1.4
Visual disturbance	4	1.1
Flatulence	4	1.1
Alanine transaminase elevation	4	1.1

Only adverse events with an incidence rate of 1 % or higher were listed

analysis of seven randomized, double-blind, placebo-controlled, dose-finding studies (treatment with olmesartan medoxomil 2.5–80 mg for 6–52 weeks) in the American and European populations, olmesartan medoxomil 20 mg per day was significantly effective in lowering BP. The mean changes in SBP/DBP from baseline to 8 weeks of treatment were $-11.3/-11.5$ mmHg [10].

The results of our study can also be compared with those of other non-comparative, prospective, observational studies of other ARBs, such as the recently published INCLUSIVE (irbesartan/hydrochlorothiazide blood pressure reductions in diverse patient populations) trial [11]. The INCLUSIVE study was an 8-week, multicentre, prospective, open-label, single-arm study that evaluated the efficacy and safety of irbesartan/hydrochlorothiazide 150 mg/12.5 mg to 300 mg/25 mg in patients with uncontrolled SBP on monotherapy (130–159 mmHg in patients with diabetes and 140–159 mmHg in the absence of diabetes). In the INCLUSIVE trial, the mean changes in clinic SBP/DBP were $-21.5/-10.4$ mmHg, and 77, 83 and 69 % of patients achieved the goal BP for SBP (<130 mmHg in patients with diabetes and <140 mmHg in the absence of diabetes), DBP (<80 and <90 mmHg) and both.

In keeping with the results of several previous studies [2, 3, 12], our study demonstrated that BP reductions on clinic measurements were much larger than on daytime ambulatory monitoring (21.2/16.0 vs. 13.9/8.0 mmHg at 24 weeks of follow-up). If home monitoring was compared with daytime ambulatory BP monitoring, the BP-lowering effects were also significantly greater with the former (17.7/12.1 mmHg) than with the latter measuring techniques. These results suggest that the three different BP-measuring methods might measure different BPs and hence have different clinical significances.

A major limitation of our study is its non-comparative design. Without a proper control group, placebo effects, observer bias and regression-to-the mean may influence the evaluation of BP-lowering efficacy especially when

assessed by clinic measurements. However, observations in non-comparative studies, such as the amplitude of changes in BP from baseline and the rate of target BP attainment, might be directly applicable in real life clinical practice. In addition, we performed home and ambulatory BP monitoring in a subset of enrolled study subjects. These more objective methods of BP measurement might help minimize potential sources of bias.

Several other limitations of our study are also noteworthy. First, ambulatory and home BP monitoring were only performed in a subset of the enrolled subjects. Second, when the present trial was initiated, guidelines for home BP monitoring had not yet been published [13, 14]. In a similar fashion to clinic BP measurement, BP at home was measured only once immediately before olmesartan medoxomil was taken. Third, our study excluded patients with isolated systolic hypertension for practical operational reasons. The results of our study hence cannot be extrapolated to this common form of hypertension in the elderly.

5 Conclusion

In mild to moderate hypertension, about two-thirds of patients treated with olmesartan medoxomil 20 mg daily may achieve the target BP after 4 weeks of treatment. With the longer term adherence to olmesartan medoxomil treatment and with the possible up-titration to 40 mg daily, the rate of attaining goal BP may further increase to approximately 80 %. In Chinese hypertensive patients, olmesartan medoxomil appears to effectively lower BP regardless of BP measurement, and has an acceptable long-term safety and tolerability profile.

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