

Olmesartan Medoxomil Evaluated for Safety and Efficacy in Indian Patients with Essential Hypertension : A Real World Observational Postmarketing Surveillance

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Abstract

Objective(s): To assess the efficacy and safety of once daily olmesartan medoxomil 20 mg in Indian patients with stage 1 essential hypertension.

Method(s): This was an open label, multicentre, real world observational postmarketing surveillance conducted in male and female patients (N=825), in age group of 18 to 65 yrs who had clinically diagnosed stage 1 hypertension (JNC-7 guidelines) and were prescribed olmesartan medoxomil 20 mg once daily as treatment. There were total of seven study visits, Visit-1 (day 1) and end of study visit-7 (end of week 8). Except for those patients who did not achieve the target BP levels, all the patients continued to receive olmesartan medoxomil 20 mg for 8 weeks, given once a day at 24 hourly intervals.

At end of surveillance (EOS; week 8) visit-7 clinical response to treatment was determined by "responder rate" and changes in level of systolic blood pressure (SBP) and diastolic blood pressure (DBP). Responder rate criteria was defined as, SBP and DBP levels of < 140 mmHg and < 90 mmHg respectively, and for hypertensive patients with diabetes mellitus SBP and DBP levels of < 130 mmHg and < 80 mmHg respectively.

Result(s): There were significant changes in mean sitting systolic and diastolic blood pressure, the primary end point of the study. From baseline visit to the end of the surveillance visit-7 (week 8), a mean change of -18.7 (147.86 to 129.16; p<.0001; 95% CI) in sitting SBP and a mean change of -14.47 (95.99 to 81.56; p<.0001; 95% CI) in sitting DBP respectively was observed with olmesartan 20 mg once daily. The response rate at the end of study was 81.82% and 70.18% for SBP and DBP respectively, in stage 1 hypertensive patients without diabetes mellitus. It was 73.38% and 65.47% respectively for SBP and DBP in patients with diabetes.

Overall efficacy of Olmesartan medoxomil 20 mg was excellent to very good in 92.5% patients, only 05 (0.6%) of patients, reported of poor efficacy. Tolerability as assessed globally was reported to be excellent to very good by 92.1% of patient, with only one patient (0.1%) reported it to be poor. The most common adverse events reported were dizziness (82.52%), headache (63%), respiratory tract infection (50.40%) and nausea (40.24%); all the AE's were mild-moderate in nature which did not require stoppage of treatment.

Conclusion(s): Our findings reiterated that Olmesartan medoxomil 20 mg once daily is not only effective in achieving the desired BP in a significant number of patients, it also shows excellent tolerability and hence compliance. Olmesartan is a valuable option for treatment of essential hypertension in adult Indian patients.

Introduction

Hypertension is fast becoming a major public health problem in India, more in urban than in rural population.¹ Hypertension is associated with diseases involving cardiovascular and renal system, it is also known that hypertension increases the risk of atherosclerotic cardiovascular diseases by an average of 2- 3 fold.² World Health Report 2002, states that cardiovascular diseases (CVDs) will be the largest cause of death and disability in India by 2020. In India prevalence of hypertension is reported to be in range of 20-40% and 12-17%, among urban and rural adults respectively, with number of people with hypertension expected to increase from 118.2 million in 2000 to 213.5 million in 2025.³ This increasing trend among others has been attributed to increase in urbanization leading to change in life style pattern, diet and increase in stress.⁴ 2.3 million deaths were caused by CVDs in India in the year 1990 and this is projected to double

by the year 2020. Hypertension is directly responsible for 57% of all stroke deaths and 24% of all coronary heart disease deaths in India.⁵

In a survey (I-Target survey) carried out to find extent of BP control among Indian hypertensive patients receiving antihypertensive medications, only 27.3% out of 3402 patients surveyed had control of BP to recommended targets.⁶ This survey underlined the need to increase awareness among Indian hypertensive patients to achieve BP target of < 140/90 mmHg^{7,8} or 130/80 mmHg in patient with diabetes mellitus^{7,8} as set by current treatment guidelines. Treatment guidelines also suggest that depending on patients need, treatment should be initiated with a low dose single agent or low dose combination of two agents.⁸ In case low dose monotherapy fails to achieve desired BP control, dose of initial antihypertensive should be increased or patient should be shifted to low dose of different agent or move to combination therapy.⁸

The benefits of BP reduction in reducing morbidity and mortality in conditions associated with hypertension have been clearly shown. In clinical trials, treating hypertension reduced

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the incidence of stroke by 35%–40%, myocardial infarction by 20%–25%, and heart failure by >50%.⁷ However, many patients fail to respond adequately to treatment and thus are not able to achieve the desired target BP. This is common with all antihypertensive agents. Drugs acting on rennin-angiotensin-aldosterone system (RAAS) like angiotensin converting enzyme inhibitors (ACEIs) and angiotensin II receptor (AT₁) blockers (ARBs) provide effective treatment of hypertension. Blockade of the RAAS by ACEIs has been shown to be effective in treating cardiovascular and diabetic conditions, including hypertension, diabetic nephropathy and heart failure, but produces side effects partly attributable to prevention of bradykinin breakdown. These side effects, especially cough, may limit compliance and occasionally can be life-threatening. Also, in the presence of ACE inhibition, angiotensin II can be produced by non-ACE-related mechanisms, which can still act on the angiotensin receptors. ARBs possess many positive features of ACEIs and fewer side effects, have therefore emerged as an alternative way of blocking the RAAS and have been used in clinical practice since 1995. Out of presently available ARBs used in the treatment of hypertension, heart failure and diabetic nephropathy, olmesartan medoxomil is the newest agent in this class.

Olmesartan medoxomil (hereafter referred as Olmesartan) is an ARB; it inhibits the actions of angiotensin II on the RAAS, which plays a key role in the pathogenesis of hypertension.⁹ Oral olmesartan 10-40 mg once daily, is recommended for the treatment of adult patients with hypertension. The recommended starting dose of olmesartan is 10 mg once daily. In patients whose blood pressure is not adequately controlled at this dose, the dose of olmesartan may be increased to 20 mg once daily as the optimal dose. Olmesartan dose may be increased to a maximum of 40 mg once daily, for patient not able to achieve target BP with 20 mg OD.¹⁰ In patients not responding adequately with olmesartan monotherapy (10-40 mg once daily) addition of hydrochlorothiazide improves response rate and blood pressure.¹¹

Although there are a number of clinical studies that support the efficacy and safety of olmesartan 20 mg once daily use in essential hypertension, the data supporting the same in Indian population is not substantial. Thus this observational postmarketing surveillance was conducted with the objective of assessing the efficacy and safety of olmesartan in Indian patients with stage 1 essential hypertension receiving olmesartan 20 mg once daily as antihypertensive treatment.

Methods

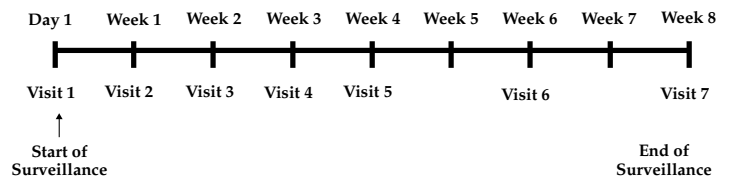
Study Population

The surveillance was conducted in male and female patients 18 to 65 years of age, with clinically confirmed hypertension stage 1 (based on an average of 2 or more recordings taken at 2 or more visits) as in the seventh report of the Joint National Committee on Prevention, Detection, Evaluation and treatment of high BP (JNC 7). Inclusion was restricted to patients with sitting SBP in the range of 140-159 mm Hg, sitting DBP in the range of 90-99 mm Hg and who were receiving olmesartan medoxomil 20 mg once daily as monotherapy.

Study Design

The surveillance was conducted as a multicentre (387 clinics all over India), open label, post marketing real world surveillance. It consisted of an 8 week surveillance period divided into six consecutive visits. Visit-1 (on day 1) included screening, enrollment and initiation of treatment. Visits 2, 3, 4

and 5 were scheduled at end of week 1, 2, 3 and 4 respectively. Subsequent visits 6 and 7 were scheduled alternatively at end of week 6 and 8 respectively.



Assessments

There were a total of seven assessment visits planned for each patient (including the screening, enrolment cum initiation visit i.e. visit-1, see study design). At visit-1 medical history, physical examination, vital signs, baseline BP and treatment history were recorded in the case report form (CRF). BP was measured for each patient at all visits in sitting position with the help of sphygmomanometer (patients resting for at least 5 minutes prior to recording), 3 readings were taken at an interval of 10 minutes and the lowest of the 3 readings were recorded in the CRF at each visit.

At subsequent visits BP was recorded as above, and also each patient was assessed for any adverse event/reaction, either spontaneously reported by the patient or noticed by the physician.

At the end of the surveillance i.e. visit-7, in addition to BP recording overall efficacy and tolerability of treatment was assessed by both doctor as well as physician and recorded in the CRF.

Primary endpoint was achievement of target systolic blood pressure (SBP) of < 140 mm Hg, diastolic blood pressure (DBP) of < 90 mm Hg and SBP < 130 mm Hg, DBP < 80 mm Hg in patients with diabetes mellitus by the end of surveillance. Patients who achieved the primary endpoint by visit-7 were considered as "responders" and rest as "nonresponders".

Statistical Analysis

The data processing was performed by capturing data into e-Case Report Forms. Data entered was checked by design for completeness and integrity. Demographic data was presented as descriptive statistics and baseline and end of surveillance (EOS) characteristics were compared by using the t-test for quantitative variables. Paired t-test was performed to assess the statistical significance of the differences between baseline and surveillance visits, under each group separately. A p value <0.05 was considered statistically significant. Overall efficacy, tolerability and safety data was presented in form frequency, as recorded at the end of surveillance. All analyses were prospectively planned and conducted on an intention-to-treat (ITT) basis. Patient data loss was kept to a minimum by defining ITT eligibility as any patient with at least one baseline and one follow-up visit.

Results

Data was received from a total of 825 patients (from 387 clinics) who participated and received treatment with olmesartan 20 mg/day. Out of these 825 patients 139 (16.84%) patients were diabetic. Patients were further divided in two sub-groups: Stage 1 hypertensives and Stage 1 hypertensives with diabetes mellitus. Demography and baseline characteristics are presented in Table 1.

There were significant changes in sitting systolic BP and sitting diastolic BP in overall study population, from baseline to

end of surveillance visit-7, with mean change of -18.7 (147.86 to 129.16; $p < .0001$; 95% CI) in sitting systolic BP levels and change of -14.47 (95.99 to 81.56; $p < .0001$; 95% CI) in sitting diastolic BP, from visit-1 to end of surveillance visit-7. There was also a significant mean reduction in heart rate of 4.82 (82.14 to 77.32; $p < .0001$; 95% CI), from baseline to end of surveillance visit-7.

A similar significant change ($p < .0001$; 95% CI) of -14.4 and -11.63 in sitting SBP and DBP respectively, in stage 1 hypertensive patients with diabetes was observed as compared to the baseline (141.22 and 92.69 mm Hg, SBP & DBP respectively). Results are presented in table 2, figure 1 and 2.

The overall "responder rate", primary end point of study was evaluated for entire study population and also the four sub-groups. The "responder rate" was defined as achievement of SBP and DBP levels of < 140 mm Hg and < 90 mmHg respectively at EOS visit, essential hypertensive (stage-1 or -2) patients and also SBP and DBP levels of < 130 mm Hg and < 80 mmHg respectively

Table 1 : Summary of baseline demographics and characteristic

	Stage-1 Hypertensive (n= 825)	Diabetic Stage-1 Hypertensive (n=139)
Demographics/characteristics [n (%)]		
male	494 (59.88%)	86 (61.87%)
female	310 (37.58%)	50 (35.97%)
Age (yr)	51.97 ± 10.08	55.51 ± 9.53
Weight (kg)	67.92 ± 10.68	70.13 ± 11.21
Heart Rate (bpm)	82.64 ± 10.80	81.37 ± 8.39
Baseline sitting SBP	147.86 ± 5.50	141.22 ± 4.33
Baseline sitting DBP	95.99 ± 7.91	92.69 ± 7.74

at EOS visit, for hypertensive patients with history of diabetes mellitus. Participants in study across all groups showed good response to study treatment; the results are presented in Table 3.

At the end of surveillance out of the total of 825 patients, only in 10 (1.2%) patients the dose of olmesartan had to be increased from 20 mg to 40 mg once daily and only 11 (1.33%) patients required any concomitant medication to achieve the desired target BP.

Safety and Tolerability

The type and frequency of adverse events were monitored and recorded at each visit in this observational surveillance. An adverse event was defined as a medical condition which was not present at screening and occurred after the first dose of study medication was instilled. A serious adverse event was defined as any untoward medical occurrence that at any dose that resulted in death, or was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, or resulted in persistent or significant disability/incapacity or a congenital anomaly/birth defect.

Only 246 (30%) patients out of a total of 825 patients reported AEs. The most common adverse events reported were dizziness (82.52%), headache (63%), respiratory tract infection (50.40%) and nausea (40.24%); all of these were mild-moderate in severity and did not result in stoppage of treatment. See table 4 and figure 3.

There were no serious adverse events, either noticed during any assessment visits or reported by patients during the entire surveillance period.

Overall efficacy of olmesartan 20 mg was assessed from excellent to very good in 92.5% patients, with only five patients (0.6%) reported poor efficacy. Global assessment of tolerability

Change in sitting SBP from baseline to EOS

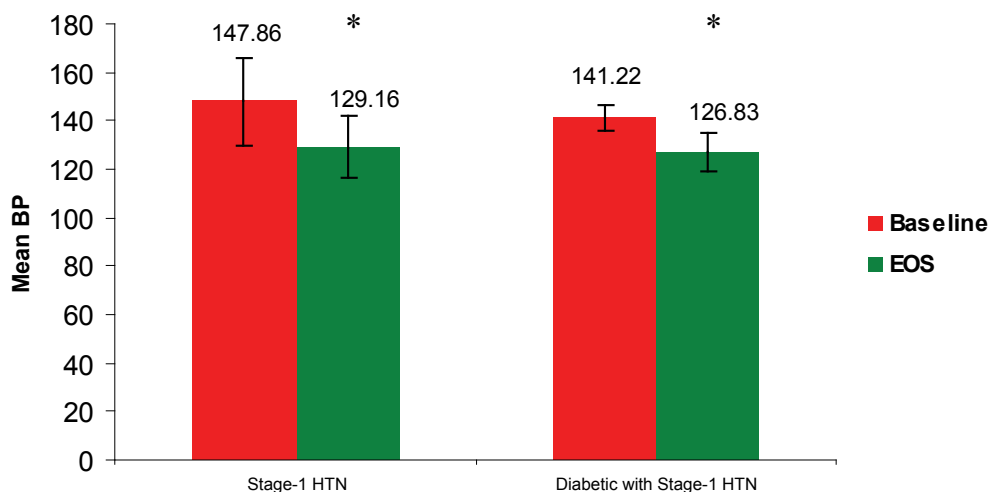


Fig. 1 : Change in sitting SBP observed in patients treated with olmesartan 20 mg given orally once daily.

*Indicates a significant ($p < 0.0001$) mean reduction in sitting SBP observed at EOS in comparison to the baseline sitting SBP; for values see Table 2.

Table 2: Change in sitting SBP and DBP from baseline to EOS

Characteristics	Baseline (Mean ± S.D.)	EOS (Visit-7) (Mean ± S.D.)	Mean Change	P value
Stage-1 Hypertension; SBP	147.86 ± 5.50	129.16 ± 8.01	-18.7	<0.0001
Stage-1 Hypertension; DBP	95.99 ± 7.91	81.56 ± 5.53	-14.43	<0.0001
Diabetic with Stage-1 Hypertension; SBP	141.22 ± 4.33	126.83 ± 6.17	-14.39	<0.0001
Diabetic with Stage-1 Hypertension; DBP	92.69 ± 7.74	81.06 ± 5.83	-11.63	<0.0001

Change in sitting DBP from baseline to EOS

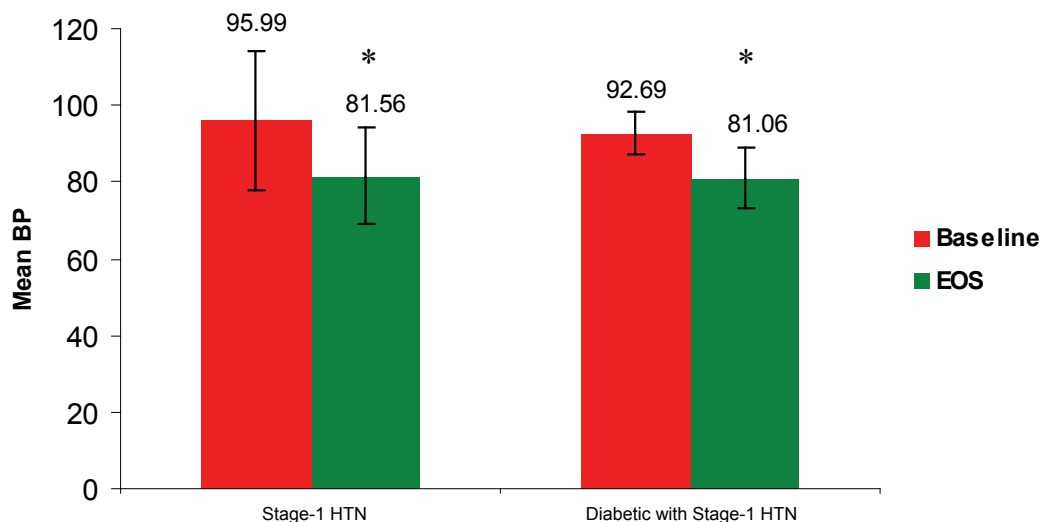


Fig. 2 : Change in sitting DBP observed in patients treated with olmesartan 20 mg given orally once daily.

*Indicates a significant ($p < 0.0001$) mean reduction in sitting DBP observed at EOS in comparison to the baseline sitting DBP; for values see Table 2.

Table 3 : Responder rate at end of week 4 (visit-5) and week 8 (visit-7)

Primary End Point Evaluated in All Enrolled (N=825)	No. of Responders (Responder rate %)
Stage-1 Hypertension (N=825)	
SBP < 140 and DBP < 90 mmHg at Visit-5	675 (81.82%)
SBP < 140 and DBP < 90 mmHg at Visit-7	579 (70.18%)
Stage-1 Hypertension with Diabetes (N=139)	
SBP < 140 and DBP < 90 mmHg at Visit-5	102 (73.38%)
SBP < 140 and DBP < 90 mmHg at Visit-7	91 (65.47%)

of treatment under surveillance varied from excellent to very good in 92.1% of patients, with only one patient (0.1%) reported it as poor. The surveillance overall showed a good compliance for olmesartan 20 mg once a day dosing in Indian patients with hypertension. See figure 4.

Discussion

The analysis of this 8 weeks open-label, real world postmarketing surveillance confirmed the efficacy and tolerability of olmesartan 20, in the treatment of hypertension. The reduction in levels of BP, both systolic (mean reduction of 18.71 mmHg) and diastolic (mean reduction of 14.43 mmHg), achieved in this study are comparable to result previously reported in randomized controlled clinical trials in hypertensive patients, with same dose of olmesartan.¹¹⁻¹⁶ The blood pressure lowering effect of olmesartan 20 mg given orally once daily, were visible within first four weeks of therapy. This was in line with previously observed early onset BP- lowering effect of olmesartan.^{10,17}

In sub-group analyses of stage 1 hypertensive patients SBP reduction of 18.7 mmHg and DBP reduction of 14.43 mmHg respectively, were achieved at EOS visit-7 (end of week 8). Significant results were achieved in stage 1 hypertensive, diabetic population in study. There was a mean change of -14.4 mmHg and -11.63 in SBP and DBP respectively in diabetic stage 1 hypertensive patients at EOS visit-7 (end of week 8). The decline in level of SBP and DBP in sub group analyses were significant ($p < 0.0001$; 95% CI). Our results confirm efficacy of olmesartan

Table 4 : Adverse event rate at end of study

Type of AE	No. of Patients	Percentage
Number of patients reported AEs out of a 825 patients = 246		
Dizziness	203	82.52%
Headache	155	63.00%
Respiratory tract infection	124	50.40%
Nausea	99	40.24%

based regimes in controlling and normalizing BP in stage 1 hypertensive patients, especially in stage 1 hypertensive diabetic patients and validates previous observations of BP-lowering effect with olmesartan.¹⁸⁻²⁰

In this real world, postmarketing surveillance, the response rate at the end of study was 81.82% and 70.18% for SBP and DBP respectively, in stage 1 hypertensive patients without diabetes mellitus. This response rate was approximately similar to previously reported with this dose of olmesartan.^{15, 21} In diabetic Stage 1 hypertensive population, 73.38% and 65.47% patients respectively, achieved primary end point (SBP < 130 mm Hg and DBP < 80 mmHg at EOS). It is known that diabetic patients are at increased risk of cardiovascular disease and olmesartan can play a major role in treating such patients. Olmesartan has shown to reduce renal vascular resistance and oxidative stress, and increase renal perfusion in addition to significantly reducing BP, in type-2 diabetic patients.²²

It is evident that intensive control of BP reduces the mortality and morbidity associated with hypertension and guidelines have been put in place to help physicians in treating patients with hypertension. Olmesartan is a selective AT₁ receptor antagonist with proven BP-lowering effect. It has rapid onset of action, with significant BP lowering effect from 2 weeks onwards.

Extensive clinical evidence from several large well designed trials and the clinical practice setting has confirmed the antihypertensive efficacy and good tolerability profile of oral olmesartan, as monotherapy or in combination with HCTZ, in patients with hypertension, including elderly patients with isolated systolic hypertension.⁹ Olmesartan appear to be more effective than older ARBs (e.g. losartan and valsartan) in reducing DBP and/or SBP in some trials. In different comparative studies,

Adverse Event Percentage

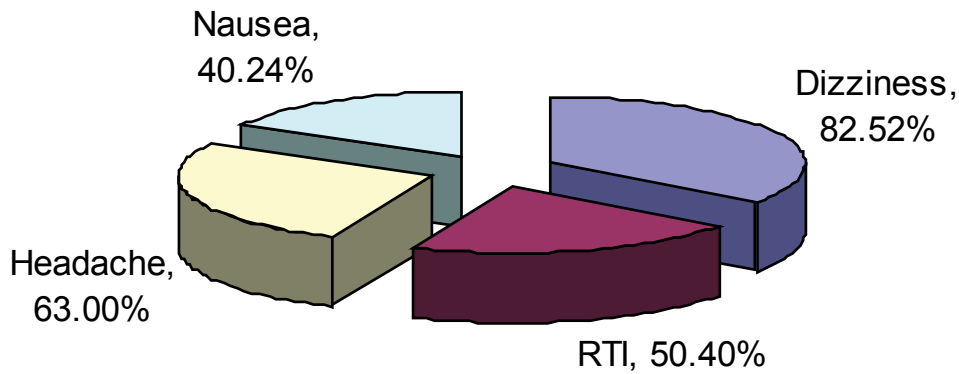


Fig. 3 : Adverse event rate at end of week study.

Overall Efficacy

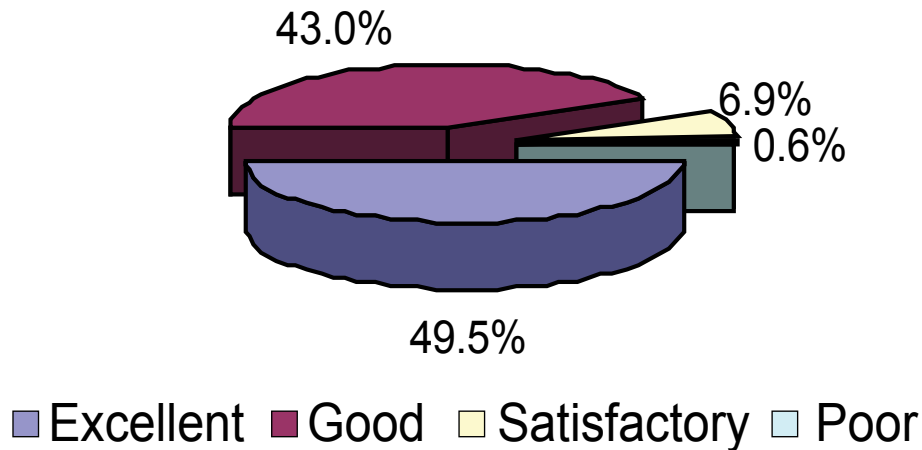


Fig. 4 : Overall efficacy and tolerability of olmesartan 20 mg once daily in Indian patients with essential hypertension as observed at the end of surveillance.

olmesartan has been shown to be at least as effective as the calcium channel blockers amlodipine²³ and felodipine²⁴ and the beta-blocker atenolol,²⁵ and significantly more effective than the ACE inhibitor captopril at the doses tested.²⁷ In addition, olmesartan medoxomil treatment regimens resulted in high BP control rates in several trials.

Also as per the existing literature good tolerability profile and consistent antihypertensive efficacy of olmesartan during the entire 24-hour dosage interval,⁹ makes it suitable for once-daily dosing.²⁷ Greater BP reduction seen with olmesartan, reduces the risk of cardiovascular and cerebrovascular events and improved efficacy makes olmesartan more cost effective than valsartan, losartan, and irbesartan.²⁸ All these factors will make the agent easy to prescribe first-line antihypertensive therapy, and should aid patient treatment compliance.

Conclusion

This real world, postmarketing surveillance reiterates that, early onset of BP-lowering effect with olmesartan 20 mg, when given as once daily dosing should help improve BP control and compliance in Indian patients with stage 1 essential hypertension with or without diabetes. At recommended doses, it is significantly effective at reducing BP with an excellent tolerability profile thus making Olmesartan 20 mg is a valuable

first-line option for treatment of Indian population with hypertension across all age groups.

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