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**SINGLE-PILL COMBINATION OF TELMISARTAN
80 MG/AMLODIPINE 5 MG PROVIDES SUPERIOR
BLOOD PRESSURE REDUCTIONS TO AMLODIPINE 5 MG
IN HYPERTENSIVE PATIENTS WHO WERE
UNCONTROLLED ON AMLODIPINE 5 MG
MONOTHERAPY**

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Objectives To investigate the efficacy and safety of the single-pill combination of telmisartan 80 mg plus amlodipine 5 mg (T80/A5 SPC) versus amlodipine 5 mg (A5) in hypertensive Asian patients who were uncontrolled on amlodipine 5 mg (A5) monotherapy (NCT01103960).

Methods Design and Methods After a 6-week open-label run-in period with amlodipine 5 mg monotherapy, patients, who failed to respond adequately to A5 (defined as seated DBP $\geq$ 90 mm Hg), underwent double-blind randomisation with 160 and 164 patients assigned to receive either T80/A5 SPC or A5 monotherapy daily. The primary end-point was change from baseline in mean seated trough DBP after 8 weeks of randomised treatment. Treatment groups were compared using an Analysis of Covariance (ANCOVA) model including treatment, country and the baseline measurement as a covariate.

Results In the full population (n=314), seated trough mean $\pm$ SE BP reductions (mm Hg) with T80/A5 vs A5 from baseline to week 8 were -16.2 ± 1.3 vs -11.7 ± 1.3 for SBP ($p<0.001$) and -12.4 ± 0.95 vs -10.2 ± 0.93 for DBP ($p=0.007$). T80/A5 provided DBP goal attainment ($<140/90$ mm Hg) in 64.5% vs 45.3% with A5 alone ($p=0.007$) and DBP response rate (<90 mm Hg or ≥ 10 mm Hg reduction) was 80.0% vs 63.5% ($p=0.0017$). The incidence of related AEs (including peripheral oedema) was low and similar in both treatments group.

Conclusions In Asian patients T80/A5 SPC provided superior BP reductions and goal rate achievement versus A5 monotherapy after 8 weeks of treatment, T80/A5 was well-tolerated and had a safety profile comparable to A5 monotherapy.