

Single-Pill Combination Therapy for the Treatment of Severe Hypertension

Single-pill combination of telmisartan 80 mg/amplodipine 10 mg is superior to telmisartan or amlodipine monotherapy with regards to blood pressure reduction in patients with severe hypertension. Joel M. Neutel, MD, Orange County Research Center, Orange County, California, USA, presented findings from the TEAMSTA severe hypertension study.

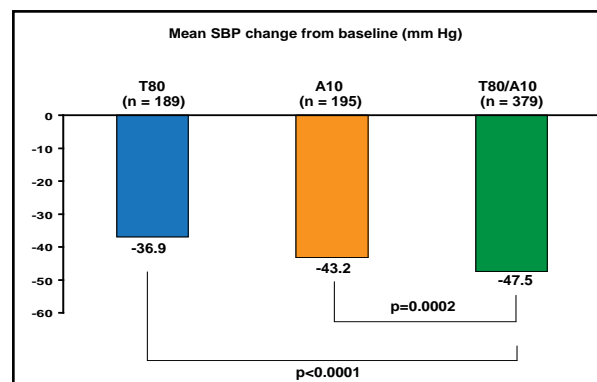
This phase III, randomized, double-blind, forced-titration, multi-center trial included 858 patients with severe hypertension (defined as mean seated systolic blood pressure [SBP] ≥ 180 mm Hg and mean seated diastolic blood pressure [DBP] ≥ 95 mm Hg). Patients were randomized to receive a single pill combination of telmisartan 80 mg/amplodipine 10 mg (T80/A10; n=421), telmisartan 80 mg (T80; n=217), or amlodipine 10 mg (A10; n=220) for a total of 8 weeks. Patients were well-matched at baseline.

The primary endpoint was change from baseline in mean seated SBP after 8 weeks of treatment. The key secondary endpoint was change from baseline in mean seated SBP after 1, 2, 4, and 6 weeks of treatment. Adverse event profiles were also evaluated to assess the safety of each treatment.

Patients treated with the single-pill combination T80/A10 demonstrated significantly greater reductions in mean SBP after 8 weeks of treatment compared with T80 alone ($p < 0.0001$) or A10 alone ($p = 0.0002$; Figure 1) with 46% of patients in the T80/A10 group achieving ≥ 50 mm Hg reduction in BP by this time. Reductions in SBP favoring T80/A10 were also observed at Weeks 2, 4, and 6, compared with T80 or A10 monotherapy ($p < 0.0001$ for all). It is important to note that a correlation was found between larger SBP reductions and higher baseline SBP. However, there did not appear to be any treatment interactions based on gender, age, race, or body mass index. Combination T80/A10 therapy also resulted in significant reductions in diastolic blood pressure versus T80 alone ($p < 0.0001$ for Weeks 1, 2, 4, 6, and 8). Therapeutic effect was observed as early as Week 1 and this effect was sustained throughout the duration of the study.

The most common adverse events were peripheral edema (11.2%), headache (5.2%), and gastrointestinal disorders (4.2%). Investigator-defined drug-related adverse events occurred in 6.9% of patients in the T80 group, 16.4% of patients in the A10 group, and 12.6% of patients in the T80/A10 group. Nine patients in the T80/A10 group discontinued treatment due to adverse events, versus 6 and 7 in the T80 and A10 groups, respectively. Overall, the treatments were safe and well tolerated.

Figure 1. Primary Endpoint.



Single-pill combination telmisartan/amplodipine was a safe and effective strategy for the treatment of severe hypertension and resulted in more favorable blood pressure outcomes than either telmisartan or amlodipine alone. Differences in SBP and DBP were observed early on and the therapeutic effect was maintained throughout the duration of treatment.



Highlights from the



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