

[7A.10] EFFECTS ON OFFICE AND HOME BLOOD PRESSURE (BP) OF LERCANIDIPINE-ENALAPRIL COMBINATION. THE FELT STUDY

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Background: Lercanidipine (L) combined with enalapril (E) has shown to reduce BP in nonresponders to monotherapy. However, no data exist on this combination when used at full doses, when given as first step treatment, and on its effects on out-of-office BP.

Objectives: To evaluate the efficacy and safety of different dose combinations of L and E on office and home BP in patients with Stage 2 hypertension.

Design and Methods: FELT was a randomized, double blind, placebo controlled, factorial study conducted in 100 centers in 7 countries. Patients with office DBP 100–109 mmHg and home DBP \geq 85 mmHg at the end of a 2-week placebo run-in period were randomized to a 10-week treatment with placebo, L (10 or 20 mg), E (10 or 20 mg), or the 4 combinations. The primary endpoint was office trough DBP while secondary efficacy parameters were office trough SBP and home SBP and DBP. Home BP was measured twice in the morning and twice in the evening for at least 3 days. Safety parameters included adverse events, laboratory tests and 12-lead ECG.

Results: A total of 1,039 patients was randomized with mean age (\pm SD) 54 ± 10 years, males 48%, BMI 30 ± 5 kg/m². Baseline BP was similar in all groups and noticeably lower for home than for office values (149/95 and 159/103 mmHg, respectively). As shown in Table, a marked placebo effect was observed on office but not on home BP. Monotherapies were often not significantly different from placebo whereas combination therapy was better than placebo at all doses and for both office and home BP. The greatest effect was observed in the L20/E20 group. Combination therapy was associated with less cough, palpitations and leg edema than monotherapies, with no increased rate of dizziness or hypotension (see Table on page e106).

Conclusion: In stage 2 hypertension the L/E combination is effective on both office and out-of-office BP, with a favorable tolerability profile.

Abstract 7A.10 – Table. Adjusted^a SBP/DBP changes (mmHg) in office (n = 1,025) and home (n = 854) BP (ITT population)

	Placebo		L 10 mg		L 20 mg	
	Office	Home	Office	Home	Office	Home
Placebo	-9.6/-8.8	-2.4/-1.5	-11.0/-10.4	-8.8/-4.6*	-13.0/-13.0	-7.7/-5.5*
E 10 mg	-14.7/-13.8*	-9.1/-6.2*	-15.8/-14.2*	-11.2/-6.4*	-17.1/-14.0*	-9.6/-6.8*
E 20 mg	-15.3/-11.3	-9.2/-5.3*	-16.1/-12.8*	-10.6/-6.5*	-19.2/-15.2*	-13.2/-7.5*

*p < 0.05 vs. placebo for both SBP and DBP. ^aAdjusted for baseline BP.

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