of AIA and Arg, which themselves appear to compete for that part of the mechanism that is resistant to ISMN.

	Brachial Systolic BP		Aortic Systolic BP		PWA (reflectance)	
	Group A	Group B	Group A	Group B	Group A	Group B
Placebo	168	160	158	146	29	19
L-arginine	161*	160	151	145	28	20
ISMN	146*	136*	131*	119*	16*	8*
ISMN + L-arginine	138**	139*	122**	121*	12*	10*

Key Words: Nitrate Therapy, L-Arginine, Systolic Hypertension

P-41

EFFICACY OF A FIXED DOSE COMBINATION OF ENALAPRIL/NITRENDIPINE IN PATIENTS NOT CONTROLLED WITH ENALAPRIL OR NITRENDIPINE MONOTHERAPY. RESULTS OF POOLED ANALYSIS OF TWO STUDIES: ENEAS-1 AND ENEAS-2

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Objective: Evaluate the efficacy of a fixed dose combination (enalapril 10mg/nitrendipine 20mg)in hypertensive patients not controlled with enalapril 10 mg (ENEAS-1)or nitrendipine 20 mg (ENEAS-2)in monotherapy.

Design: A pooled analysis of two prospective, multicenter, multinational (Germany, Belgium, Spain and France) randomized,phase III clinical trials (ENEAS-1 and ENEAS-2)has been done. Both studies were developed simultaneously, in similar sites, and with the same methodology and design. Brieftly: hipertensive patients (stage I and II of JNC VI report)not controlled(diastolic pressure> or = 90mmHg) after 6 weeks of monotherapy with enalapril 10 mg (ENEAS-1) or nitrendipine 20 mg (ENEAS-2), were randomised, in a double-blind design to either continue monotherapy or begin combination therapy, for a further 12 weeks. The principal variable was the reduction of diastolic blood pressure (DBP) in comparison with baseline. The secondary variables were sistolic blood pressure (SBP) decrease, diastolic, systolic and global response rate.

Results: A total of 784 patients were included in the pooled analysis (360 from ENEAS-1 and 424 from ENEAS-2). An statistically significant difference has been stated in favour of the combined therapy versus the monotherapy in all the efficacy objectives. The main efficacy results refered to the per protocol population (PP)are shown in the following table:The results in the intention-to-treat population yielded similar figures.

Conclusions: The results obtained by the pooled analysis of ENEAS-1 and ENEAS-2 demonstrate a better efficacy of the fixed dose combination enalapril 10mg/nitrendipine 20mg vs a monotherapy group (enalapril alone or nitrendipine alone) on DBP, SBP, and on the response rate.

Efficacy variable	Analysis population	Enalapril or Nitrendipine in monotherapy	Enalapril/ Nitrendipine	p value
DBP	PP	↓ by 5.7 mmHg	↓ by 8.3 mmHg	p = 0.001
SBP	PP	↓ by 8.6 mmHg	↓ by 10.9 mmHg	p = 0.044
Diastolic response rate	PP	50.2%	64.5%	p = 0.002
Systolic response rate	PP	37.7%	48.8%	p = 0.015
Global response rate	PP	40.9%	54.4%	p = 0.004

Key Words: Fixed Dose Combination, Enalapril Nitrendipine, Antihypertensive Therapy

P-42

EFFICACY AND SAFETY OF VARDENAFIL, A SELECTIVE PHOSPHODIESTERASE 5 INHIBITOR, IN MEN WITH ERECTILE DYSFUNCTION ON ANTIHYPERTENSIVE THERAPY

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Background: Vardenafil is being evaluated for the treatment of erectile dysfunction (ED). Since ED frequently develops in men with hypertension, the efficacy and safety of vardenafil in men who received antihypertensive therapy (aHT) was examined.

Methods: In this pooled analysis of two randomized, double-blind pivotal Phase III studies, men with ED for ≥6 months received vardenafil 5, 10, or 20 mg or placebo for 12 or 26 weeks. Of 1401 men valid for safety, 545 took at least one aHT during treatment. Efficacy variables included the Erectile Function Domain of the International Index of Erectile Function, and diary assessments of penetration and maintenance of erections. Adverse events (AEs) were reported for all patients. Potentially clinically relevant alterations in standing BP (SBP ≤90 mm Hg and decrease from baseline ≥20 mm Hg, DBP ≤50 mm Hg and decrease from baseline ≥15 mm Hg) or HR (>120 BPM and increase from baseline >15 BPM) were assessed in a subgroup of patients taking vardenafil (n=363) or placebo (n=95) within 11 minutes to 5 hours after study drug administration.

Results: Vardenafil (5, 10 and 20 mg) significantly improved EF Domain, penetration, and maintenance rates compared to placebo irrespective of aHT use ($p<0.001$).

The most common treatment-emergent AEs for men on vardenafil receiving aHT (≥5%) were headache (11%), rhinitis (7%), and vasodilation (6%) and were similar or lower than those not on aHT. Minimal potentially clinically significant decreases in standing BP occurred on vardenafil (SBP, n=2 non-aHT patients and DBP, n=1 aHT patient). No clinically significant elevations in standing HR were observed in vardenafil-treated patients.

Conclusion: In this study, vardenafil was well tolerated and improved erectile function for men with ED on aHT. Little evidence of an influence of vardenafil on BP was observed when measured within 5 hours irrespective of aHT use.

	Placebo	Vardenafil 5 mg	Vardenafil 10 mg	Vardenafil 20 mg
aHT	±	±	±	±
EF domain score, LS* mean (n)	13.9 (228)/ 14.8 (100)	19.2 (214)/ 18.7 (124)	21.3 (221)/ 19.8 (129)	21.8 (220)/ 20.7 (121)
Penetration, %, LS mean (n)	47.5 (222)/ 49.8 (101)	69.4 (218)/ 64.3 (123)	77.2 (220)/ 72.3 (126)	81.2 (217)/ 74.2 (121)
Maintenance, %, LS mean (n)	27.0 (221)/ 31.3 (101)	52.9 (217)/ 50.3 (123)	65.8 (220)/ 56.7 (126)	66.2 (217)/ 58.1 (121)

** - Least squares mean*

Key Words: Vardenafil, Anti-Hypertensive Medications, Erectile Dysfunction

P-43

EFFICACY AND TOLERABILITY OF FIXED-DOSE FORMULATIONS OF AMLODIPINE/BENAZEPRIL FOR TREATMENT OF HYPERTENSION

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Background: A large (n=7912) multicenter, open-label, practice-based clinical trial was undertaken to assess the efficacy and tolerability of