



HYVET

HYPERTENSION IN THE VERY ELDERLY TRIAL

Implications in clinical practice

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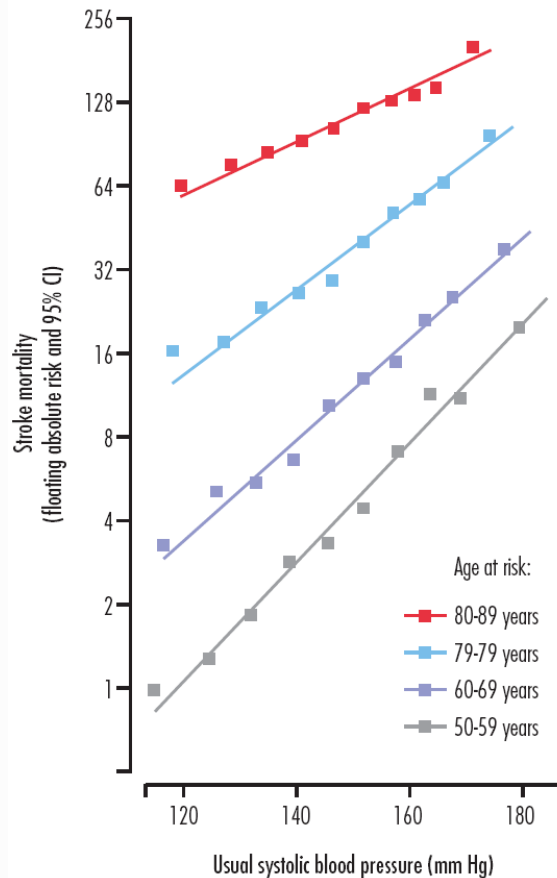
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AGENDA

- HYVET: Rationale and design
- HYVET: The results
- HYVET: The implications in clinical practice

CV risk increases with SBP and age



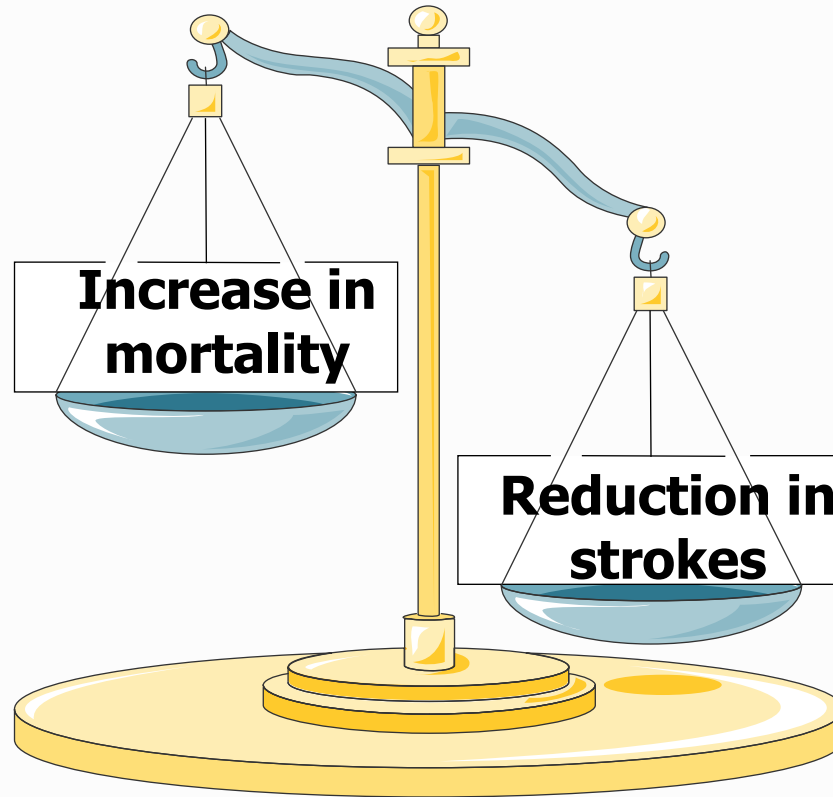
- Age and SBP are two major components of CV risk
- SBP predicts CV risk
(Williams B. *Lancet* 2008)

Prospective studies collaboration. *Lancet*. 2002;360:1903-1913.
Williams B et al. *Lancet*. 2008; 371: 2219-2221

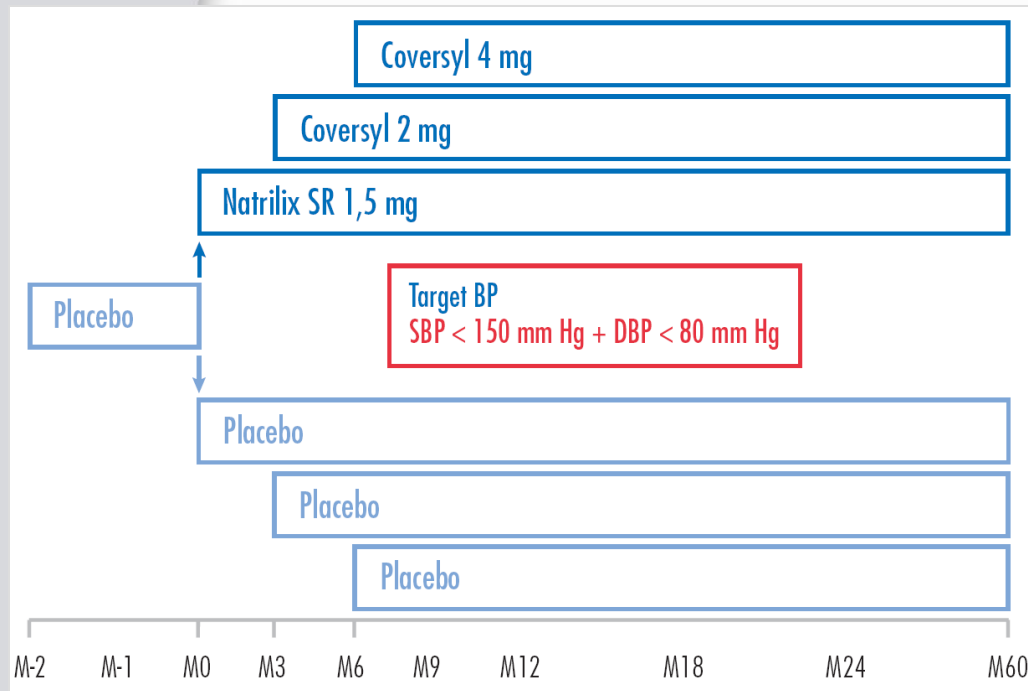
Benefit Seen in Clinical Trials

- Meta-analysis (n=1670) (*Gueyffier et al. 1997*)
 - ✓ 36% reduction in the risk of stroke (BENEFIT)
 - ✓ 14% ($P=0.05$) increase in total mortality (RISK)
- Hypertension in the Very Elderly Trial (HYVET) pilot results (n=1273) similar to meta-analysis (*Bulpitt et al. 2003*)

To treat or not to treat fragile hypertensive patient?



The HYVET main trial

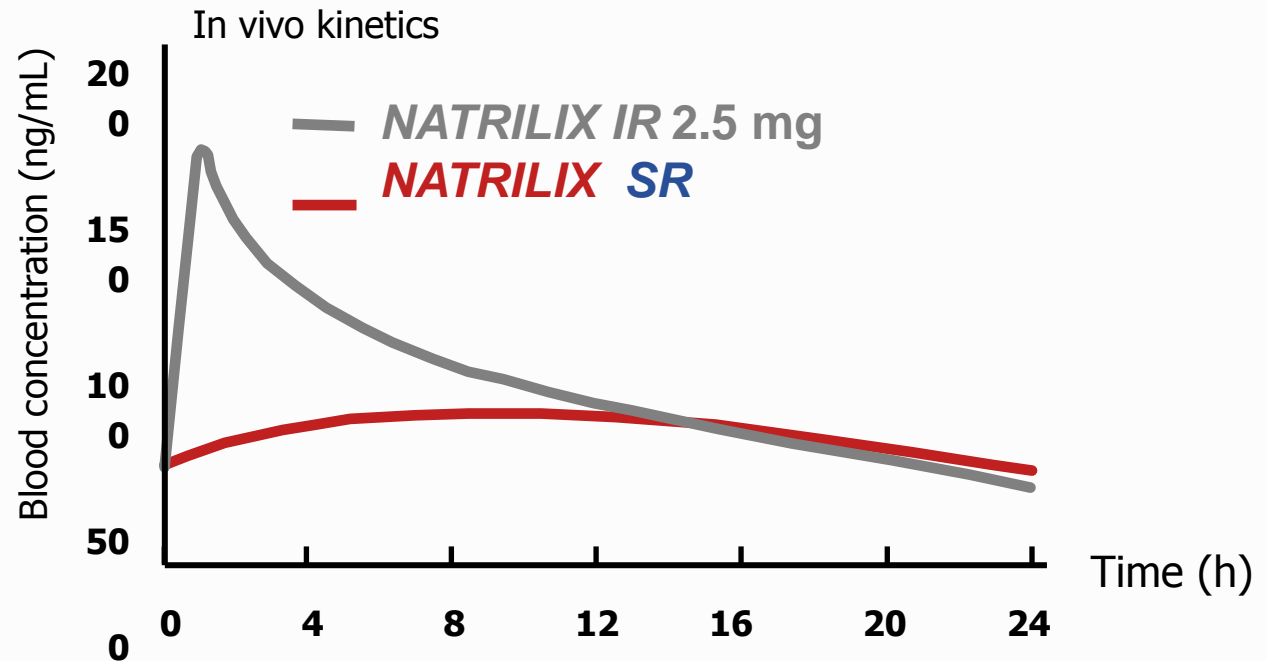


- International, multicenter, randomized, double-blind, placebo-controlled
- 13 countries and 195 centres
 - ✓ 3845 randomised
 - ✓ Western Europe (86) Eastern Europe (2144), China (1526), Australasia (19), Tunisia (70)
- *Primary end point:* All strokes (fatal and nonfatal)

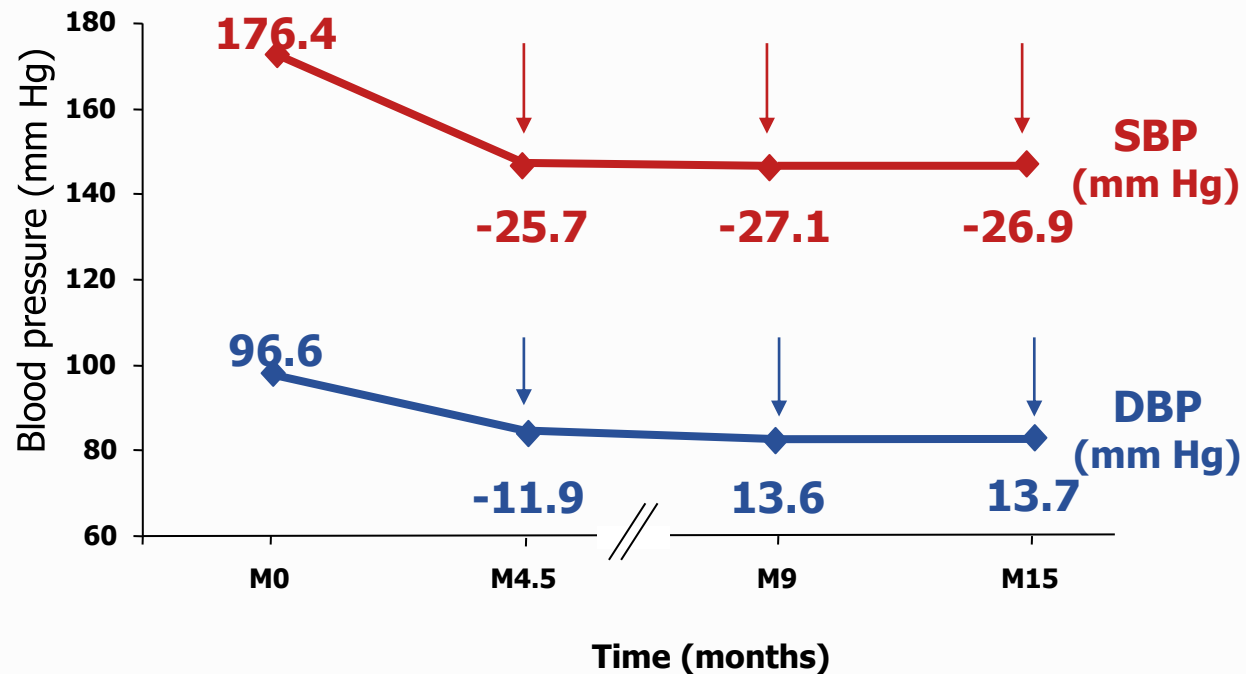
Why was **Natrilix** SR chosen?

Smooth pharmacokinetic profile due to unique SR formulation

Elimination of unnecessary peaks in plasma concentration



Efficacy maintained over long term

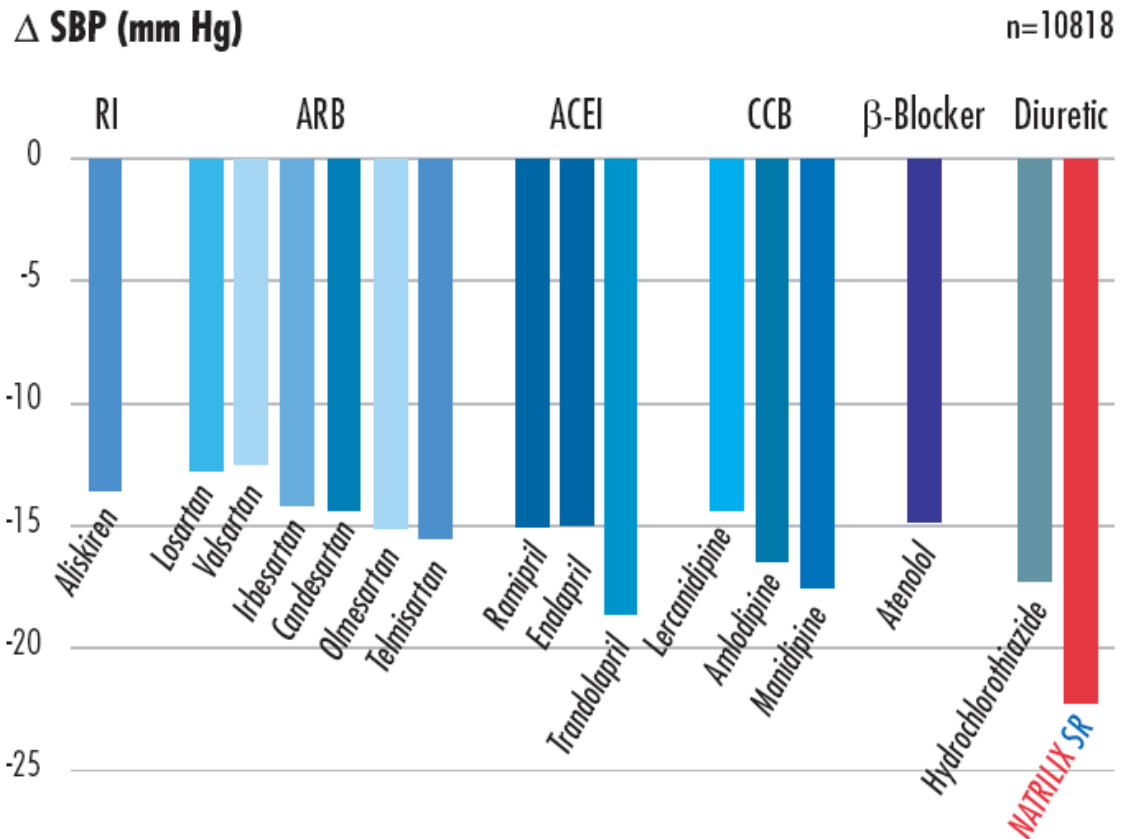


NATRILIX[®] SR

Superior SBP efficacy in all hypertensive patients

BAGUET

Natrilix SR lowers SBP by 8mmHg over than other antihypertensives.

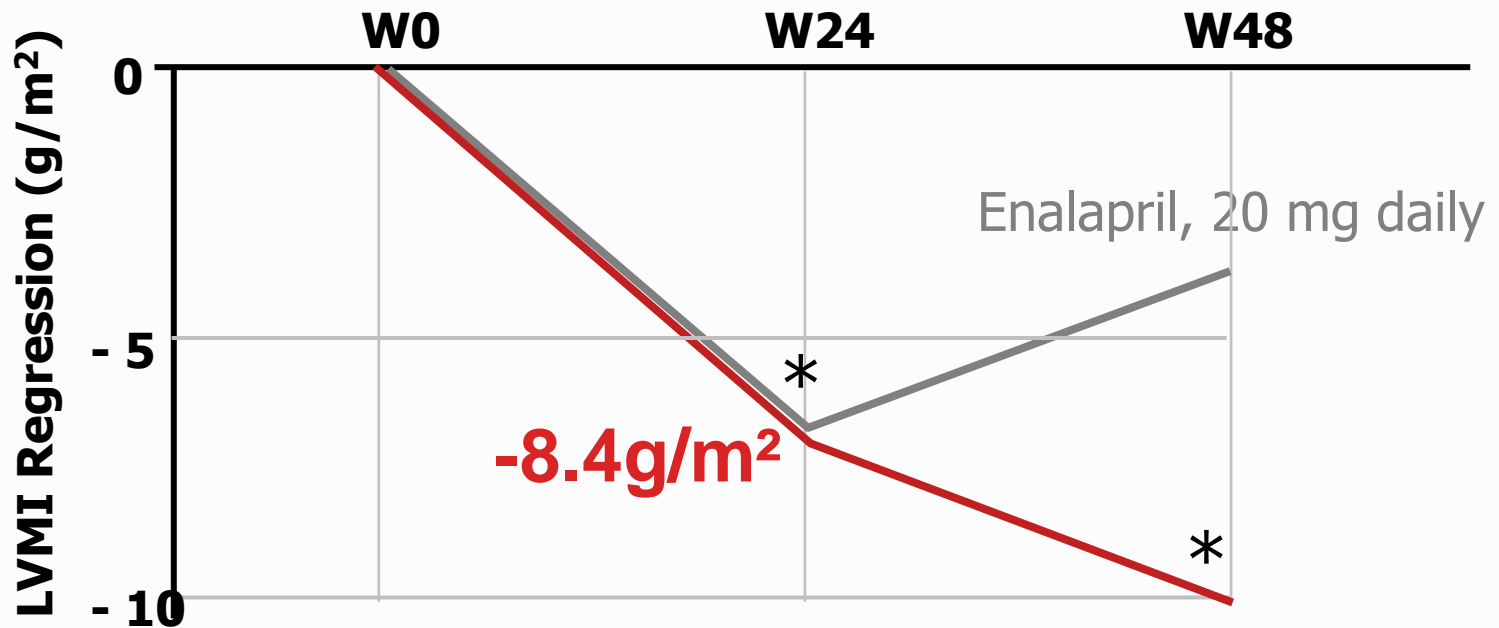


NATRILIX[®] SR

Proven heart protection
in all hypertensive patients



Natrilix SR regresses LVH



NATRILIX SR

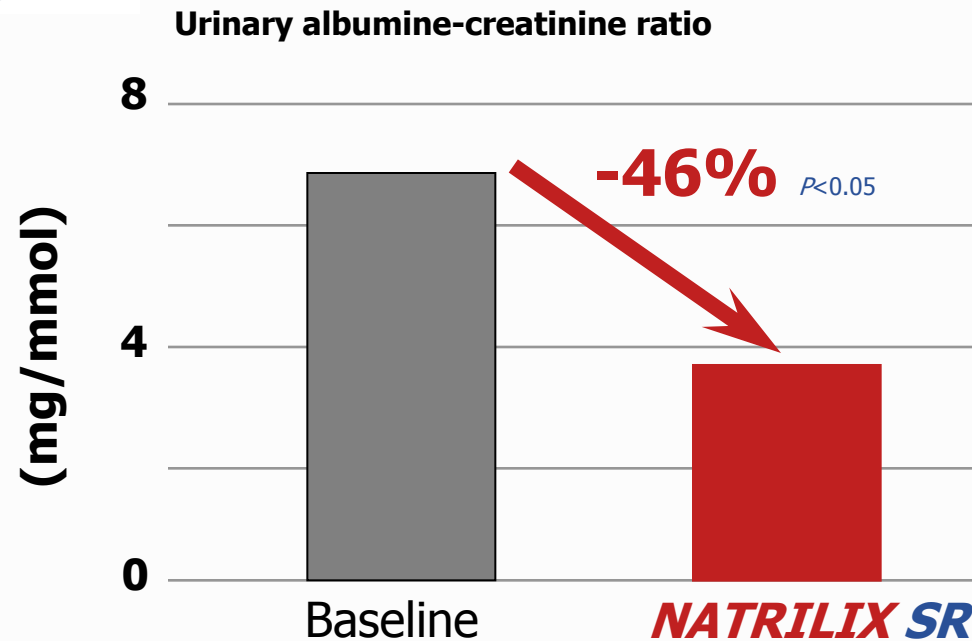
n=411

* $P < 0.05$

Duration=11 months



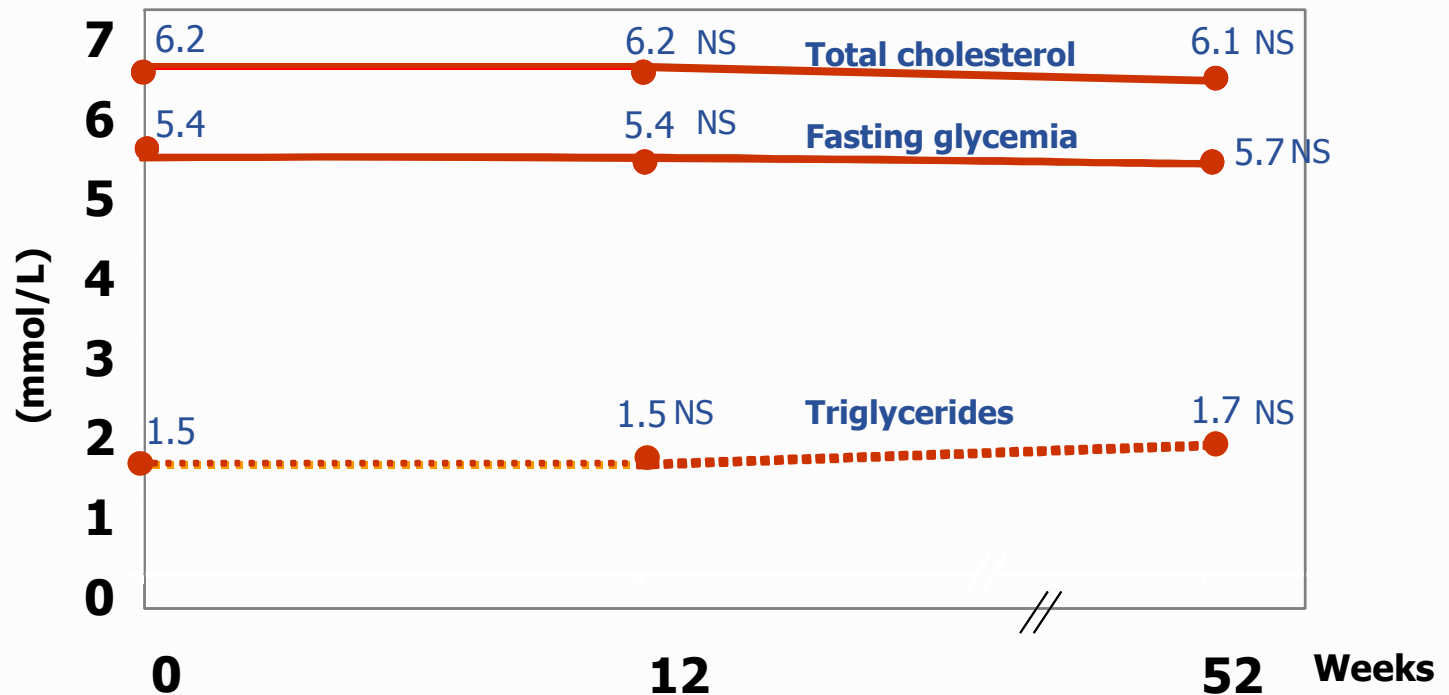
Natrilix SR reduces microalbuminuria



Type 2 diabetic hypertensive patients with microalbuminuria

Duration=1 year

No change in lipid and glucose metabolism
over the long term

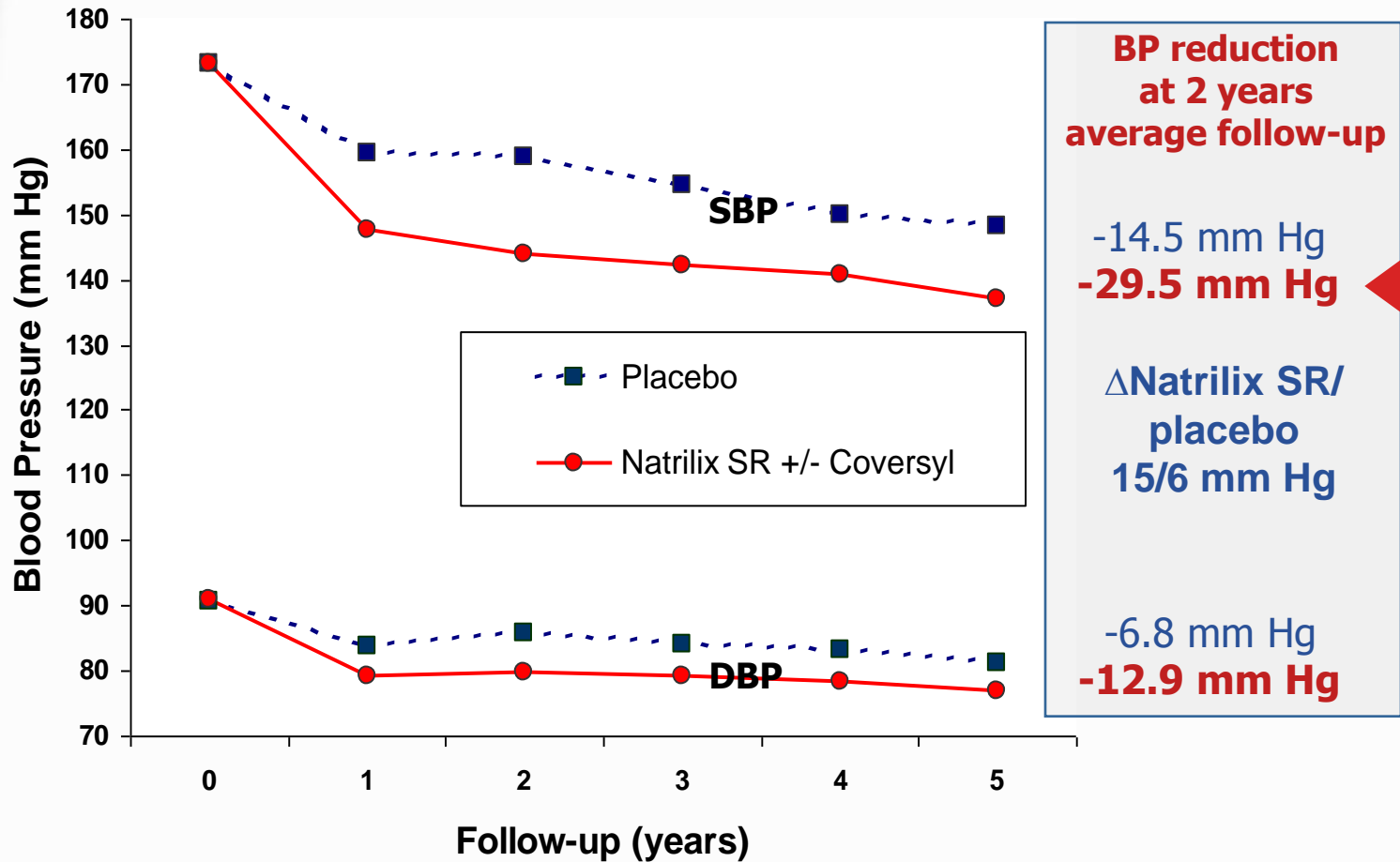


HYVET FINDINGS

THE NEW ENGLAND JOURNAL OF MEDICINE

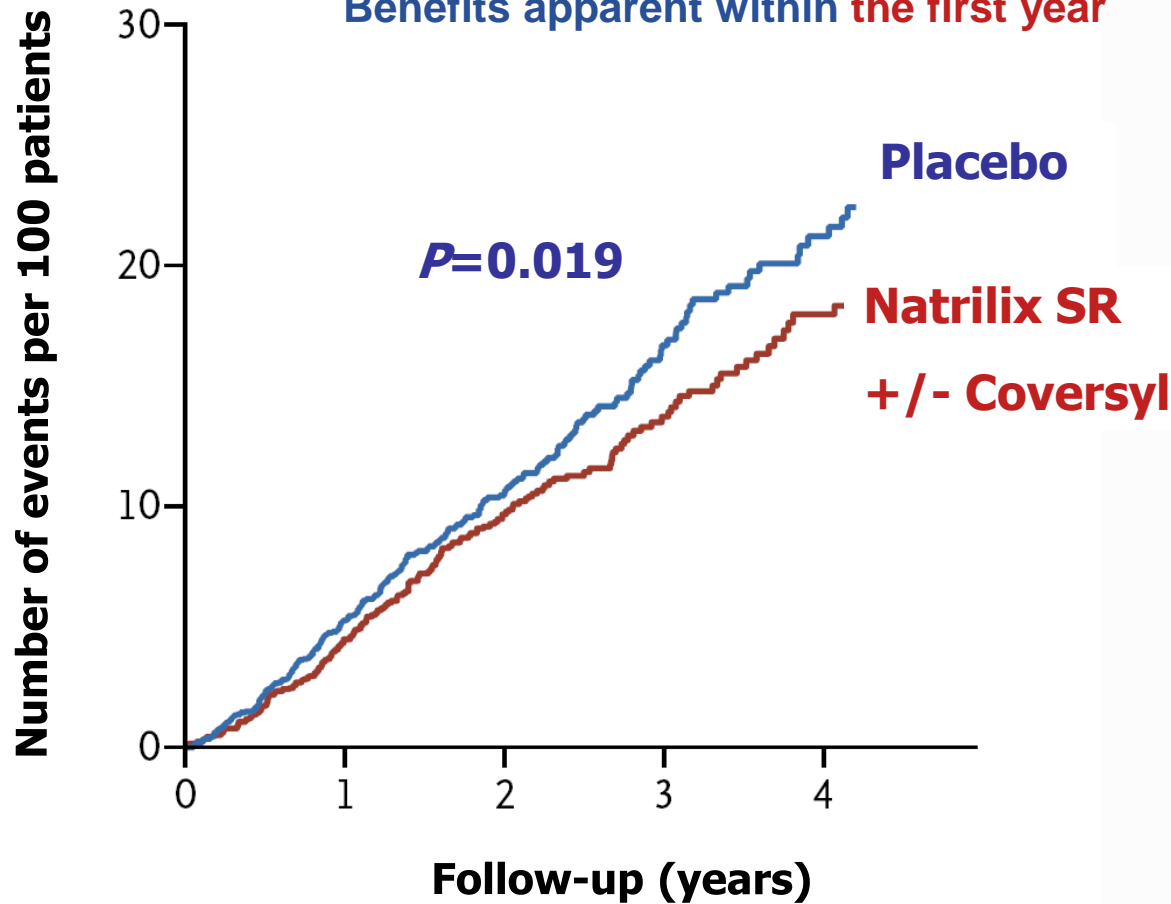
The unique and first evidence that antihypertensive treatment with *Natrilix SR* with or without perindopril is beneficial in one of the most fragile hypertensive population.

Blood pressure reduction

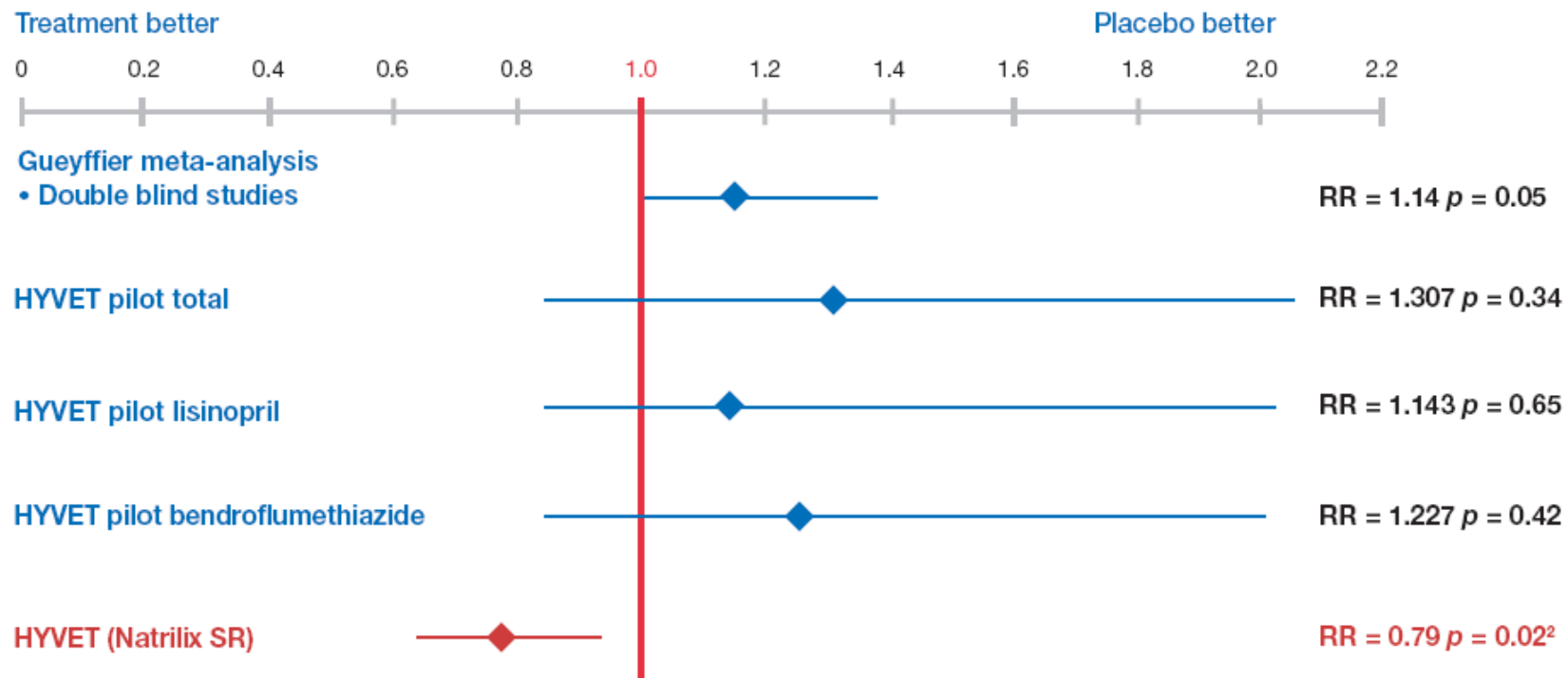


Total mortality (21% risk reduction)

2-year treatment in 40 patients prevents 1 death
Benefits apparent within **the first year**

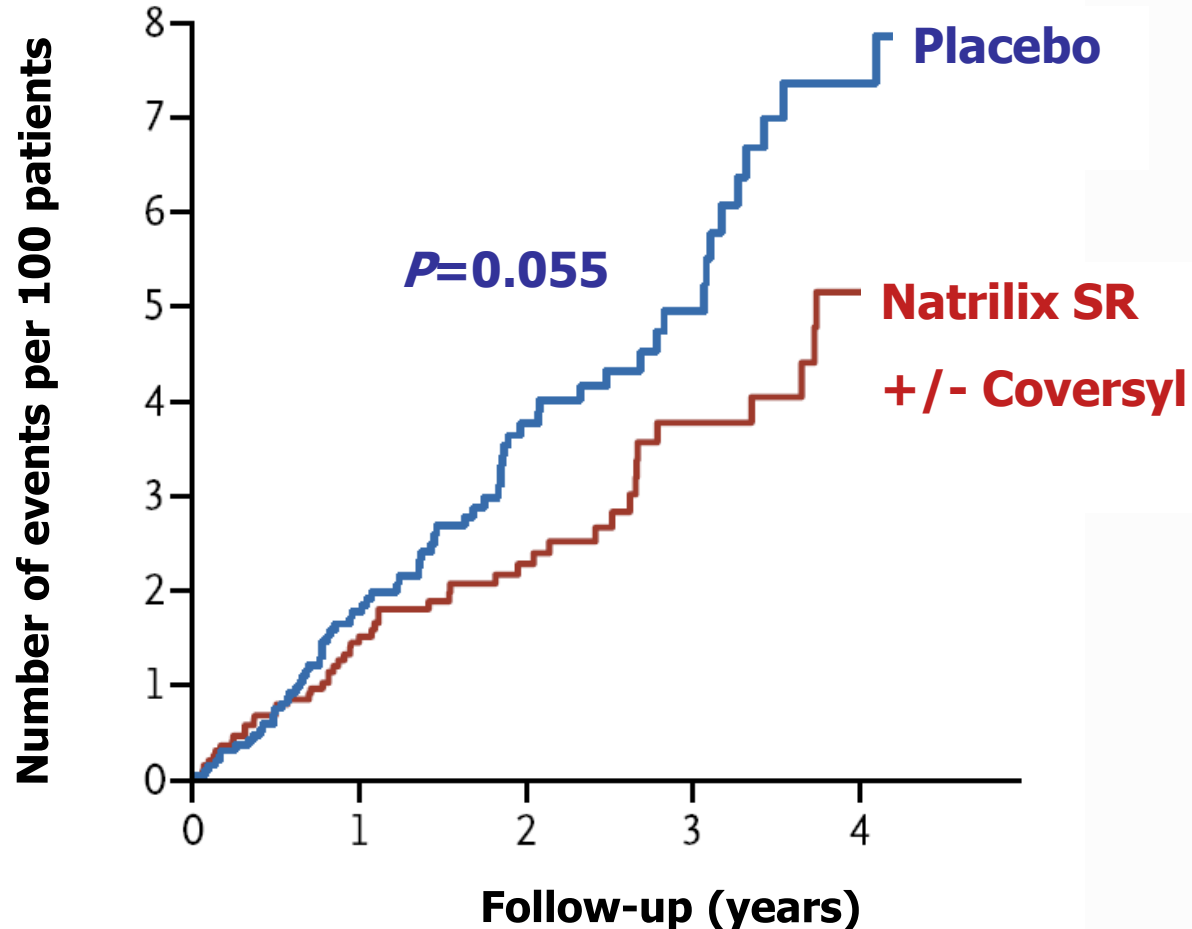


Natrilix SR the only one to cut all-cause mortality by one fifth

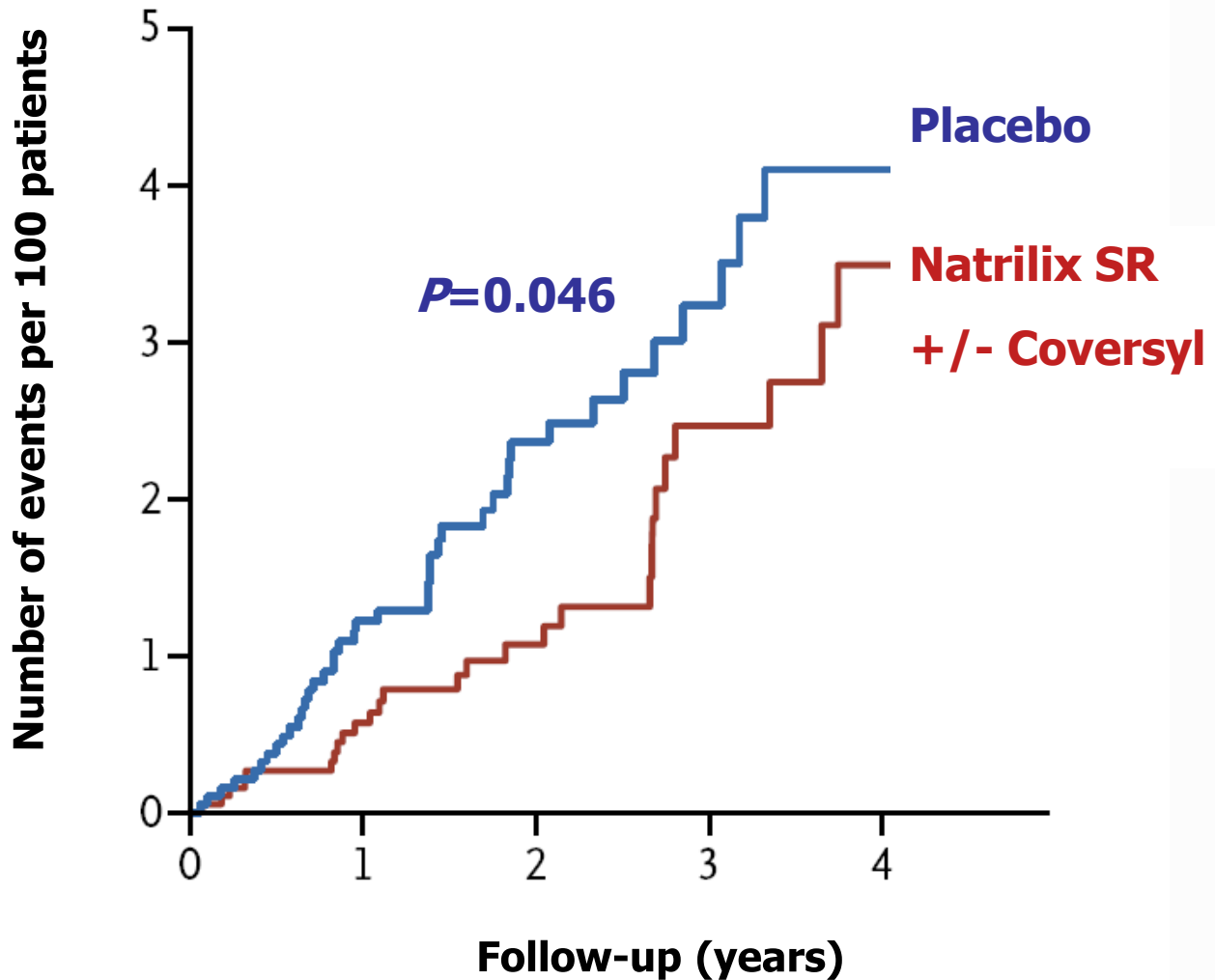


All stroke (30% risk reduction)

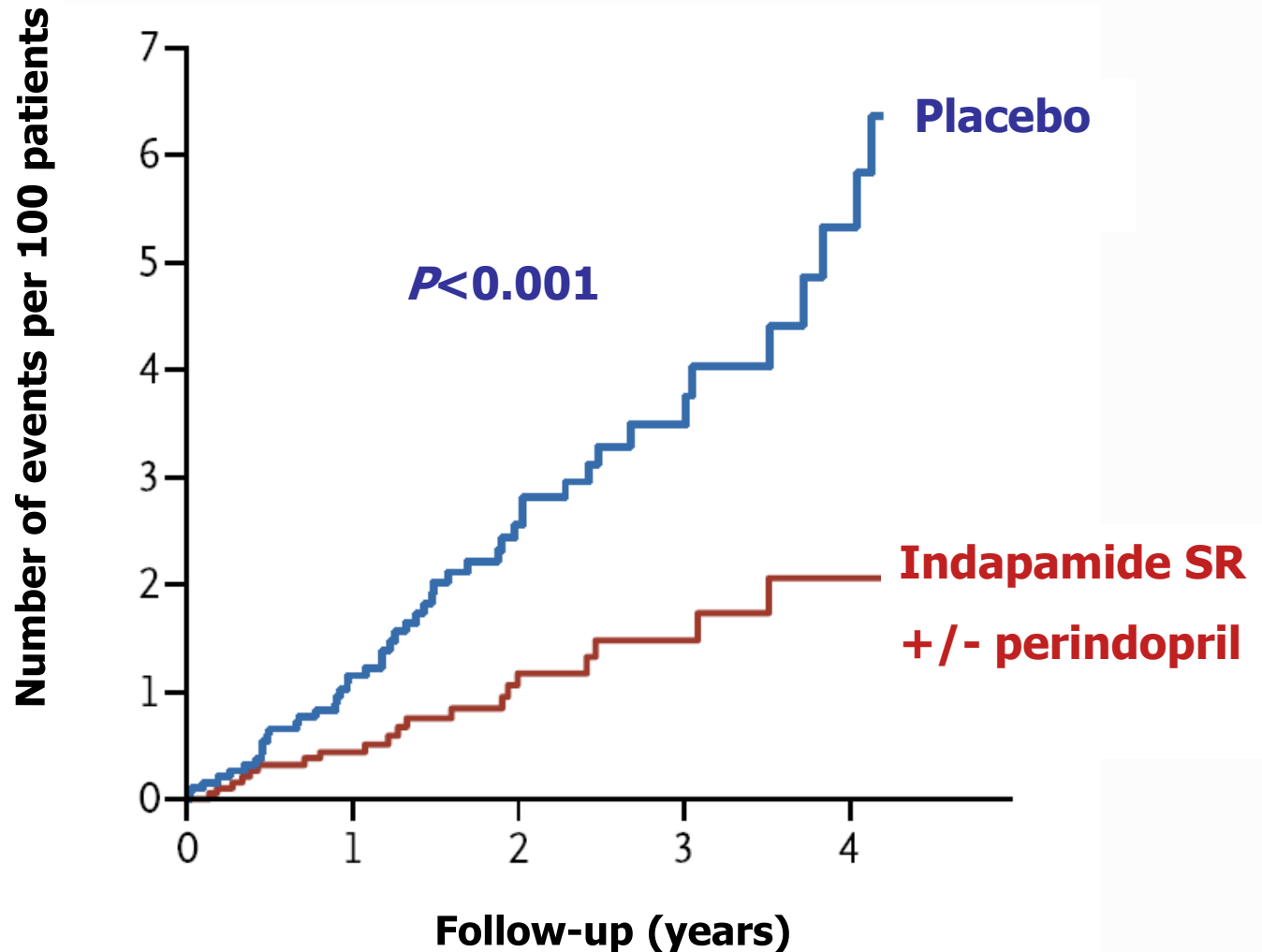
2-year treatment in 94 patients prevents 1 stroke
Benefits apparent within **the first year**



Fatal stroke (39% risk reduction)



Heart failure (64% risk reduction)



Biochemical changes (2-year cohort)

- No significant differences between the groups with regard to changes in serum...
 - ✓ Potassium
 - ✓ Uric acid
 - ✓ Glucose
 - ✓ Creatinine
- At 2 years, 73.4% of patients were receiving the combination treatment in the active group (85.2% placebo)

Natrilix SR stands out in the diuretic class in terms of metabolic neutrality

Why is HYVET so important for clinical practice?

No matter how old you are – who wants to suffer a stroke?

HYVET results are unequivocal

Natrilix SR +/- Coversyl cuts:

- The risk of death by 21%
- The risk of stroke by 30%
- The risk of heart failure by 64%

HYVET is a landmark clinical trial and today's results will change the practice of medicine across the world"

Prof B. Williams, UK

The “me too” response to path breaking trials.

(“My drug is also good for such patients”)

Well, maybe yes or maybe no !

Only *Natrilix* SR can
ensure HYVET results

- **Natrilix SR is a simple, effective, and well tolerated treatment strategy that:**
 - Provides superior **reduction in SBP**
 - Protects **target organs** from fatal consequences of hypertension
 - » Heart: reversal of LVH, reduction in heart failure
 - » Kidney: reduction in microalbuminuria
 - » Brain: protection against stroke
 - Preserves **metabolic profiles**

The maybe's for other drugs:

- To quick a drop in BP?
- Compensatory tachycardia?
- Shorter duration of action?
- Side effects?
- Biochemical (metabolic) effects?

We simply do not know. Until other antihypertensive drugs have been tested Natrilix SR-based regimen remains the only documented treatment modality showing such life-saving benefits in a such fragile hypertensive patients.

As pointed out by Prof Bryan Williams, University of Leicester, UK, "HYVET is the most important trial in recent times with regard to patient benefits and its potential for impacting on blood pressure guidelines".



NATRILIX[®] SR

Thank you



HYVET

HYPERTENSION IN THE VERY ELDERLY TRIAL

& NATRILIX[®] SR

Questions