The Hypertension in the Very Elderly Trial (HYVET)

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Presented at ACC 2008 in Chicago

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HYVET Trial: Background

- Blood pressure reduction has been shown to prevent vascular events such as stroke

- There has been no conclusive results suggesting benefit in treating patients with hypertension over 80 years of age

- HYVET's goal was to evaluate the benefits and risks of providing medical care to very elderly individuals presenting with hypertension

HYVET Trial: Study Design

3845 patients $\geq$ 80 years with continual hypertension and systolic blood pressure $\geq$ 160 mm Hg prior to randomization
Prospective. Randomized. Double Blind. Placebo-Controlled. Mean follow-up 1.8yrs

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Active Treatment
1.5 mg Indapamide (SR)
n=1933

Placebo
Matching Dose
n=1912

2 yrs. follow-up

- Primary Endpoint: fatal and non-fatal strokes
- Secondary Endpoints: death from: stroke, cardiovascular causes, cardiac causes and any cause

HYVET Trial: Baseline Characteristics

Characteristic	Active Treatment (n=1933)	Placebo (n=1912)
Age (years $\pm$ SD)	83.6 $\pm$ 3.2	83.5 $\pm$ 3.1
Female (%)	1174 (60.7)	1152 (60.3)
Blood Pressure (mm Hg)		
While sitting		
Systolic	173.0 $\pm$ 8.4	173.0 $\pm$ 8.6
Diastolic	90.8 $\pm$ 8.5	90.8 $\pm$ 8.5
While standing		
Systolic	168.0 $\pm$ 11.0	167.9 $\pm$ 11.1
Diastolic	88.7 $\pm$ 9.3	88.6 $\pm$ 9.3

HYVET Trial: Baseline Characteristics

Characteristic	Active Treatment (n=1933)	Placebo (n=1912)
CV disease (%)	223 (11.5)	229 (12.0)
Hypertension (%)	1737 (89.9)	1718 (89.9)
Antihypertensive Tx (%)	1241 (64.2)	1245 (65.1)
Stroke (%)	130 (6.7)	131 (6.9)
Myocardial Infarction (%)	59 (3.1)	62 (3.2)
Heart Failure (%)	56 (2.9)	55 (2.9)
Current Smoker (%)	123 (6.4)	127 (6.6)
Diabetes (%)	132 (6.8)	131 (6.9)

HYVET Trial: Baseline Characteristics

Characteristic	Active Treatment (n=1933)	Placebo (n=1912)
Total Cholesterol	5.3 ± 1.1	5.3 ± 1.1
HDL-Cholesterol	1.35 ± 0.38	1.35 ± 0.37
Serum Creatinine	88.6 ± 20.5	89.2 ± 20.5
Uric Acid	280.4 ± 79.3	279.0 ± 81.3
Body-Mass Index	24.7 ± 3.8	24.7 ± 3.5
Heart Rate	74.5 ± 9.1	74.5 ± 9.3
Systolic Hypertension (%)	625 (32.3)	623 (32.6)
Orthostatic Hypotension (%)	152 (7.9)	169 (8.8)

HYVET Trial: Outcomes
Main Fatal and Nonfatal End Points in the Intention-to-Treat Population

End Point	Rate per 1000 Patient-Yr (No. of Events)		Unadjusted Hazard Ratio	
	Indapamide	Placebo	(95% CI)	p-value
	No. (%)			
Fatal/nonfatal stroke	12.4 (51)	17.7 (69)	0.70 (0.49-1.01)	0.06
Death from stroke	6.5 (27)	10.7 (42)	0.61 (0.38-0.99)	0.046
Death from any cause	47.2 (196)	59.6 (235)	0.79 (0.65-0.95)	0.02
Death from non-CV/ unknown causes	23.4 (97)	28.9 (114)	0.81 (0.62-1.06)	0.12
Death from CV cause	23.9 (99)	30.7 (121)	0.77 (0.60-1.01)	0.06

HYVET Trial: Outcomes
Main Fatal and Nonfatal End Points in the Intention-to-Treat Population

End Point	Rate per 1000 Patient-Yr (No. of Events)		Unadjusted Hazard Ratio	
	Indapamide	Placebo	(95% CI)	p-value
	No. (%)			
Death from cardiac cause*	6.0 (25)	8.4 (33)	0.71 (0.42-1.19)	0.19
Death from heart failure	1.5 (6)	3.0 (12)	0.48 (0.18-1.28)	0.14
Any fatal or nonfatal MI	2.2 (9)	3.1 (12)	0.72 (0.30-1.70)	0.45
Any fatal or nonfatal heart failure	5.3 (22)	14.8 (57)	0.36 (0.22-0.58)	<0.001
Any fatal or nonfatal cardiovascular event**	33.7 (138)	50.6 (193)	0.66 (0.53-0.82)	<0.001

*Death from cardiac causes was defined as fatal myocardial infarction, fatal heart failure, and sudden death.**Any cardiovascular event was defined as death from cardiovascular causes or stroke, myocardial infarction, or heart failure.

- The trial drew upon healthier-than-normal patients, so its data cannot be extrapolated to frailer people

- Evidence to support diagnosis of a stroke was not always available as some patients' deaths were not monitored and an autopsy was not performed

HYVET Trial: Summary

- Lowering the blood pressure of hypertensive patients over the age of 80 is associated with reductions in total mortality and rate of cardiovascular events.