

Risks and benefits of estrogen plus progestin in healthy postmenopausal women

Women's Health Initiative Investigators

JAMA 2002; 288: 321-333

The trial in a nutshell

- 16,608 healthy postmenopausal women 50-79y (average 63.3)
- Randomised to receive oestrogen + progestin daily (8,506) or placebo (8,102)
- Followed for 3.5-8.5 years, average 5.2
- Primary outcome CHD
- Primary adverse outcome invasive breast cancer
- Stopped 3+ years early because invasive breast cancer exceeded monitoring boundary

Key Process measures

Measure	HRT	Placebo
Stopped pills	42%	38%
Gynaecologist unblinded	3,444	548
Hysterectomy	248	183
LDL	-12.7%	0
HDL	+7.3%	0
Blood pressure	+1.5mm	0

Key Outcome measures

Measure	HRT	Placebo
CHD events	37/10,000 py	30/10,000 py
Strokes	29/10,000 py	21/10,000 py
Venous TE	34/10,000 py	16/10,000 py
Inv breast ca	38/10,000 py	30/10,000 py
Bowel cancer	10/10,000 py	16/10,000 py
Hip fractures	10/10,000 py	15/10,000 py
Global index	170/10,000 py	151/10,000 py

Global Index

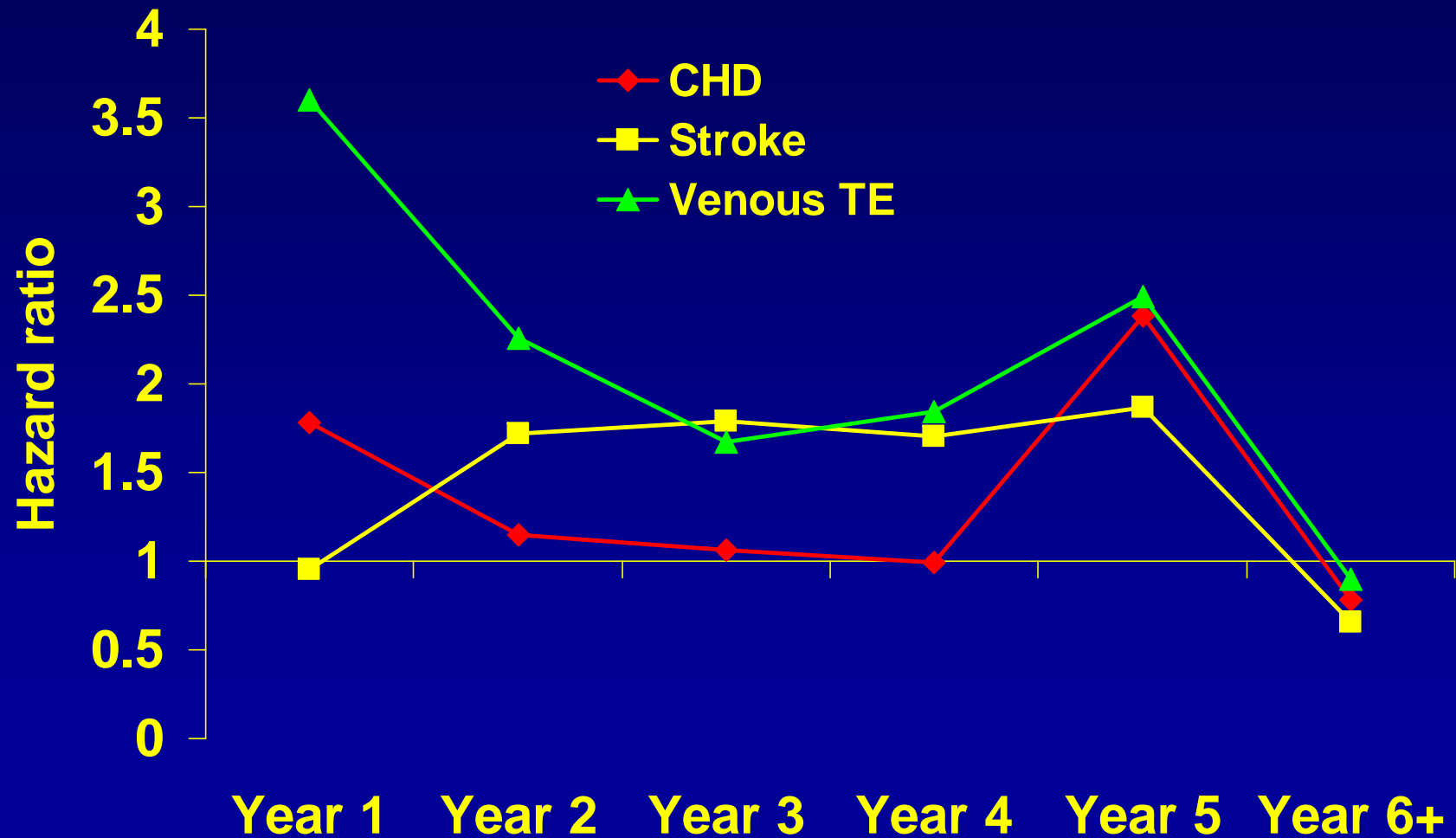
Global index event counted first time a woman has any of:

- Coronary heart disease event
- Stroke
- Pulmonary embolism
- Breast cancer
- Endometrial cancer
- Colorectal cancer
- Hip fracture
- Death from some other cause

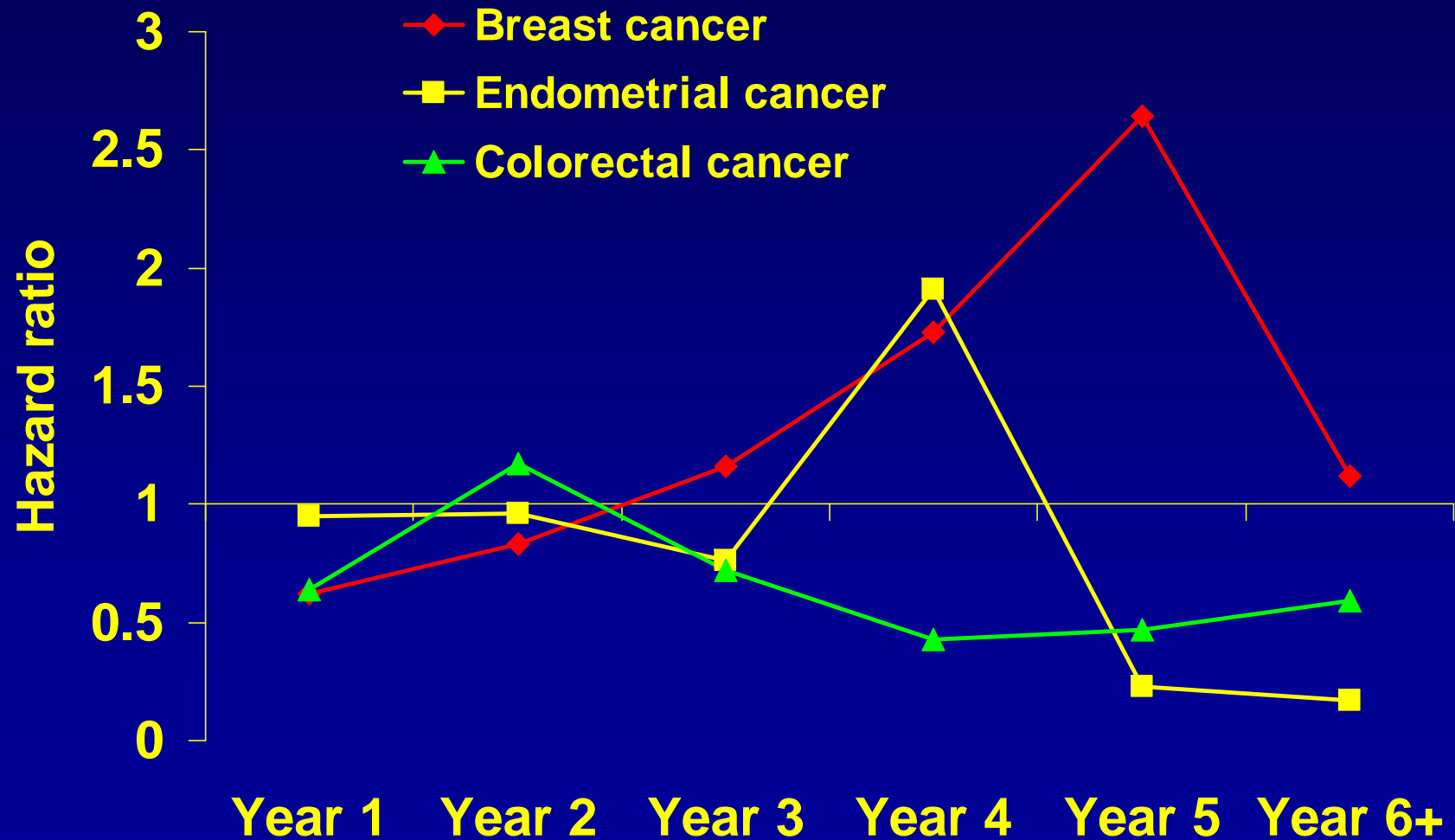
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Hazard ratios by follow-up year



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