Is HRT safe?

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- 1. Background to the issue the basis of hormone therapy (HRT)
- 2. Current thinking on HRT:
 - What the science and scientists say is HRT right for you?
 - Scientific studies: Million Women Study (MWS) a UK study
 - Women's Health Initiative (WHI) a US study
- 3. The complexity of HRT risk and NICE guidelines on HRT prescribing
- 4. Summary is HRT safe?
- 5. What are the natural alternatives to HRT?

Background to the issue

Early 1990s – large scale studies were set up.

HRT widely prescribed for:

- relieving menopausal symptoms
- preventing osteoporosis
- preventing heart disease (not all studies confirmed its benefits)

Q. where does the evidence come from?

WHI (Women's Health Initiative) Hormone Replacement
 Study
 American trials designed to study CV risk

 MWS (Million Women Study)
 A UK Study designed to investigate the risk of breast cancer in women using different types of HRT

1996 (publ. in 2003)

Findings from these studies (2002)

- 1. Little to no evidence if reduced risk of heart disease. In fact, there was evidence for an increased risk of blood clots and stroke.
- 2. Increased risk of breast and ovarian cancer
- 3. Most of the effects of HRT (positive and negative) are seen whilst taking HRT and disappear once HRT is stopped.

The WHI study was abruptly halted.

Q. what are the more recent findings?

- An 18-year follow-up study of the participants in the WHI study provides more reassurance:
 - no greater risk of dying in the subsequent 18 years that not for those on HRT
 - Risks of all-cause mortality, CV mortality or cancer mortality is **NOT** associated with HRT
- 2. Analysis of the WHI study data focussed on the **age** of the participants. The findings show that:
 - older women were at high risk
 - benefits outweighed the risks:
 - a. for healthy women < 60 years
 - b. within 10 years of onset of the menopause
 - women who started HRT in early menopause tended to live longer than women who didn't take HRT (observational study evidence)

Evidence from 30 clinical trials show that:

women who began HRT **before** 60 years had 39% lower risk of death than women who didn't take HRT (pooled statistical analysis)

Newer formulations* of hormones (since the WHI study began) may further minimise the risks.

*Newer formulations include:

- transdermal oestrogen (patches)
- micronized progesterone
- SSRIs (typically prescribed as antidepressants) relieve hot flushes and other menopausal symptoms

The complexity of HRT risk (MWS data)

- breast cancer risk is a good example of this complexity
- risks are greater:
 - for combined HRT than oestrogen-only HRT
 - when HRT is started around the time of the menopause rather than later
 - for thinner than fatter women (BMI is a consideration) because oestrogen is a fat-soluble hormone so fatter women produce more oestrogen and adding extra oestrogen makes less of a difference compared to thinner women who have less fat to absorb circulating oestrogen)
- HRT-associated risks for breast cancer ranged from over two-fold increased risk to no added risk depended on:
 - a. type of HRT
 - b. timing of use
 - c. BMI
- Differing patterns of association with different forms of HRT on:
 - a. heart disease
 - b. stroke
 - c. fractures
 - d. ovarian cancer

41% of UK medical schools do not have mandatory menopause education on the curriculum. Many UK universities expect their students to gain menopause education whilst on their GP training placements:

- this is a risky practice because it relies entirely on whether the GP trainer is knowledgeable about menopause and HRT advice
- many GPs have little or no formal menopause education and not familiar with current guidance.

The Verdict: HRT isn't all bad... nor all good. There are benefits as well as risks.

Benefits	Risks
Relieve symptoms to allow women to	Benefits usually outweigh the risks
function in their day-to-day lives	
Relief of unpleasant symptoms such as:	HRT is a medicine and comes with SE.
hot flushes	Specific SE of oestrogen and
night sweats	progesterone (see table)
mood swings	
 vaginal dryness 	
↓ sex drive	
Prevent osteoporosis	Other risks:
	 breast cancer
	 blood clots
	heart disease
	strokes

Most of the effects (benefits and risks) are seen while women are on HRT, then disappear once HRT is stopped). Risks only persist as long as HRT is taken.

No hysterectomy (uterus present):

R_x oestrogen + progesterone (or progestin*) since progesterone is needed to balance the effects of oestrogen otherwise the oestrogen can stimulate the growth of the uterine lining (endometrium) and ↑ the risk of endometrial/uterine cancer

^{*}progestin = synthetic progesterone (progesterone-receptor agonists)

Synthetic HRT	Bioidentical HRT
 Made in a lab from chemicals that are structurally similar to 	 Hormone preparations made from plant sources that are promoted as
endogenous hormones but NOT identical	being similar or identical to human hormones
 They linger in the body as they have no 'time sense' like 	 Can be standardised to deliver the correct dose so can be 'custom
endogenous hormones	made'

<u>Hysterectomy (uterus absent):</u> Rx oestrogen only

Recommendations:

- find the best product and delivery method that best suits each person
- minimise the amount of HRT taken (lowest possible dose)
- seek regular follow up care
- make healthy lifestyle choices

Weaning off HRT

Gradually decreasing your HRT dose is usually recommended because it's less likely to cause your symptoms to come back in the short term.

Side effects of oestrogen	Side effects of progestogen
The main side effects of taking oestrogen include: • bloating	The main side effects of taking progestogen include: • breast tenderness
 breast tenderness or swelling swelling in other parts of the body feeling sick leg cramps headaches indigestion vaginal bleeding 	 swelling in other parts of the body headaches or migraines mood swings depression acne tummy (abdominal) pain back pain vaginal bleeding
Any side effects usually improve over time, so it's a good idea to persevere with treatment for at least 3 months if possible.	As with side effects of oestrogen, these will usually pass after a few weeks.
These side effects will often pass after a few weeks. To ease side effects, try: • taking your oestrogen dose with food, which may help feelings of sickness and indigestion • eating a low-fat, high-carbohydrate diet, which may reduce breast tenderness • doing regular exercise and stretching, to help leg cramps	If they persist, a GP may recommend switching to a different way of taking progestogen, changing the medicine you're taking, or lowering your dose.

NICE Guidelines for Prescribing HRT (2015)

- contraindications and cautions
- routes of administration
- choice of hormone
- regimen (perimenopausal + menopausal women)
- adverse effects

Women's Health and the NHS

- Responses from 100,000 women surveyed (call to collect views made in Spring 2021)
- Part of a wider 'women's health strategy'
- More needs to be done to close the 'gender gap' in NHS services
- Sexism/gender inequality blamed for failings around prescribing of HRT

- Other inequalities around:
 - postcode lottery for IVF
 - disproportionate ↑ in gynaecological waiting lists
 - failings in HRT prescribing
 - treatment failings in endometriosis

Q. So what are the alternatives?

1. Herbal Medicine (instead of HRT, specific herbs/phyto-oestrogens, holistic management address other symptoms)

Non-Hormone Alternatives (clinical trial evidence for supplements)

Isopropanol = extract from black cohosh (shown to reduce hot flushes and

night sweats compared to placebo

Soya Extracts = phyto-oestrogens also show promise especially 30mg

genistein (but can take up to 12 weeks to take effect)

- 2. Massage Therapy especially stress management and sleep
- 3. Practical Measures (Holistic Management):
 - clothing (layering up)
 - stress management techniques (eg. yoga, tai-chi, massage, meditation etc..)
 - EOs or wax melts
 - connecting with nature (eg. gardening, walking in woodland/open spaces etc...)
 - counselling
 - diet (↓caffeine, ↓alcohol, ↑fermented foods)
 - exercise (\(\gamma\)resistance training to improve bone/joint health)



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