PRACTICE

Hormone replacement therapy for the primary prevention of chronic diseases: recommendation statement from the Canadian Task Force on Preventive Health Care

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Recommendations

- Given the balance of harms and benefits, the Canadian Task Force on Preventive Health Care recommends against the use of combined estrogen–progestin therapy and estrogen-only therapy for the primary prevention of chronic diseases in menopausal women (grade D recommendation).
- For women who wish to alleviate menopausal symptoms using hormone replacement therapy (HRT), a discussion between the woman and her physician about the potential benefits and risks of HRT is warranted.

In the early 1990s the Canadian Task Force on Preventive Health Care issued a grade B recommendation for counselling perimenopausal women regarding the use of estrogen replacement therapy (ERT) for the primary prevention of osteoporotic fractures.[1] At that time, the large observational studies that constituted the best available evidence further indicated the potential for ERT to confer a cardioprotective benefit to women[2–4] and to prevent bone loss.[1,5] The early large observational studies indicated a small but significant risk of breast cancer,[6–8] and of endometrial cancer among women with an intact uterus taking unopposed estrogen therapy.[9]

The evidence base has grown in the last decade, as numerous clinical trials have been conducted on the potential positive and negative effects of hormone replacement therapy (HRT) for various chronic conditions. This statement is based on 3 systematic reviews conducted by the task force[6,10,11] and by others[12] of the potential benefits and harms of HRT, and it incorporates the results of the estrogen-plus-progestin and the estrogen-only trials of the Women's Health Initiative (WHI), stopped early in May 2002 and February 2004 respectively because of safety concerns.[13,14] This statement does not review the evidence for use of HRT in the treatment of menopausal symptoms; instead, it provides a brief discussion of considerations that may be useful for clinicians and their patients when deciding whether HRT should be taken for symp-

This table is meant as a guide for discussion with patients; an individual's risk profile may alter the balance of harms and benefits.

Table 1: Annual rates of events prevented or caused per 10 000 women taking combined estrogen–progestin or estrogen-only hormone replacement therapy (HRT) versus placebo

	Combined estrogen–progestin HRT		Estrogen-only HRT	
Outcome	Prevented	Caused	Prevented	Caused
Cardiovascular disease events				
Coronary artery disease events	–	7*	–	–
Stroke	–	8*	–	12†
Thromboembolism	–	18*	–	7†
Total cardiovascular disease events	–	25*	–	24†
Cancer				
Breast (invasive)	–	8*	–	–
Ovarian	–	–	–	2‡
Colorectal	6*	–	–	–
Cholecystitis				
< 5 yr of therapy or placebo use	–	25§	–	–
≥ 5 yr of therapy or placebo use	–	53.5§	–	–
Fracture				
Hip	5*	–	6†	–
Vertebra	6*	–	6†	–
Other (includes wrist)	39*	–	–	–
Total	44*	–	56†	–

*These data are from the Women's Health Initiative (WHI) estrogen-plus-progestin trial,[13,21] in which the HRT regimen was the daily combination of oral conjugated equine estrogen (0.625 mg) and medroxyprogesterone acetate (2.5 mg).
†These data are from the WHI estrogen-only trial,[14] in which the daily estrogen-only HRT regimen was oral conjugated equine estrogen (0.625 mg).
‡These data are from Lacey et al.[32]
§These data are from the systematic review and meta-analysis by Nelson et al.[12]

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Evidence and clinical summary

Cardiovascular disease

- Women in the estrogen–progestin arm of the WHI[13,21] had an increased relative risk (RR) of an adverse outcome from cardiovascular disease of 22% (hazard ratio [HR] 1.22, adjusted 95% confidence interval [CI] 1.00–1.49, or 25 more events per 10 000 person-years of HRT use [157 v. 132 events per 10 000).[21] For women in the estrogen-only arm of the WHI, there was no difference in coronary artery disease events (HR 0.91, adjusted 95% CI 0.72–1.15); however, the risk of stroke increased by 39%, with an additional 12 events per 10 000 person-years (HR 1.39, adjusted 95% CI 0.97–1.99). The risk of thromboembolic events increased by 33%, with an additional 7 events per 10 000 person-years. The rate of total cardiovascular disease events, including stroke, was increased by 12% in the estrogen-only group, with an additional 24 events (HR 1.12, adjusted 95% CI 0.97–1.30).[14] These findings are consistent with some, but not most, previous observational studies and secondary prevention trials,[22,23] as reviewed by Abramson[10] and summarized in the Apr. 27 issue of *CMAJ*.[24]

Cancers

- Long-term current use of HRT with unopposed estrogen or combination therapy is associated with an increased risk of breast cancer. This risk increases with duration of use.[12] The WHI estrogen-plus-progestin results indicated an HR of 1.26 (adjusted 95% CI 1.00–1.59), or an additional 8 cases of invasive breast cancer per 10 000 person-years of HRT use (38 v. 30 events per 10 000 person-years) after 5.2 years.[13] The Million Women Study recently showed that, compared with women who never used HRT, those who were using HRT were 1.66 times more likely to develop breast cancer and 1.22 times more likely to die of it.[25] Recent data suggest that combination therapy with progestin may confer a higher risk than unopposed estrogen.[13,25–27]
- There is some evidence that long-term HRT is associated with an increased risk of ovarian cancer,[28–30] but studies have shown mixed results.[31,32]
- Both short- and long-term unopposed estrogen therapies are associated with an increased risk of endometrial cancer among women with an intact uterus (RR 2.3, 95% CI 2.1–2.5).[33] Combination therapy, especially when progestins are used for more than 10 days, is not associated with any significant increased risk, as indicated by both the WHI results (HR 0.83, adjusted 95% CI 0.29–2.32) and the meta-analysis of observational studies by Grady and associates[33] (overall RR 0.8, 95% CI 0.6–1.2).
- Use of unopposed estrogen or combination therapy (regardless of dose or duration) is associated with a decreased risk of colorectal cancer. The results of the WHI (HR 0.63, adjusted 95% CI 0.32–1.24, or 6 fewer cancers per 10 000 person-years of HRT use [10 v. 16 events per 10 000]) are consistent with the previous meta-analysis of observational studies by Grodstein and associates,[34] which found an RR of 0.80 among women who had ever used HRT (95% CI 0.74–0.86) and 0.66 among current HRT users (95% CI 0.59–0.74). How recently HRT was used seems to confer the benefit, rather than merely its use in the past.[34,35]
- The WHI estrogen–progestin arm[13] and the estrogen-only arm[14] reported composite HRs for all cancers included in their analyses of 1.03 (adjusted 95% CI 0.86–1.22) and 0.93 (adjusted 95% CI 0.75–1.15) respectively, which is consistent with findings from previous studies.

Osteoporotic fractures

- Although there is fair evidence that HRT is effective in the primary prevention of fractures, the risks of this therapy may outweigh the benefits.[14,36]

Other outcomes

- Women who use HRT are at increased risk of:
  - venous thromboembolic events (deep vein thrombosis and pulmonary embolism) (HR 2.11, adjusted 95% CI 1.26–3.55)[13]
  - cholecystitis in the first 5 years (RR 1.8, 95% CI 1.6–2.0); this risk is increased with sustained use (RR 2.5, 95% CI 2.0–2.9)[37]
  - probable dementia, with the recent WHI Memory Study results indicating an HR of 2.05 (95% CI 1.21–3.48, or an additional 23 cases of dementia per 10 000 person-years (45 v. 22 cases per 10 000 person-years)[38]
  - worsening urinary incontinence in women with existing incontinence (summary odds ratio 1.51, 95% CI 1.26–1.82).[39]
- HRT has not been found to improve health-related quality of life, especially in asymptomatic women,[40] nor to prevent mild cognitive impairment.[41]

Clinical implications

- Before the publication of the WHI estrogen–progestin trial results, it was estimated that 22% of Canadian women aged 45–64 were currently using HRT, with highest use (33%) among those 50–54 years of age.[42] Although many women have been taking combination HRT for the preven-

tion of chronic diseases, the current evidence indicates that the harms outweigh the benefits, demonstrating an increased risk of breast cancer, venous thromboembolism, pulmonary embolism, stroke, myocardial infarction, probable dementia, cholecystitis and worsening incontinence, and a decreased risk of osteoporotic fractures and colorectal cancer. In addition, HRT use by postmenopausal women without menopausal symptoms does not improve health-related quality-of-life outcomes, including depression, sleep, sexual functioning and overall self-rated quality of life.[40] The recently released results of the WHI estrogen-only trial,[14] showing an increased risk of stroke and a decreased risk of hip fractures, further support the notion that HRT, whether unopposed or in combination with progestin, should not be used for the prevention of chronic diseases.

- Many women, however, especially those in early menopause, seek HRT to control menopausal symptoms,[43] in particular vasomotor effects, an outcome for which there is demonstrated benefit.[44] For women who wish to alleviate menopausal symptoms using HRT, a discussion between the woman and her physician of the potential benefits and risks is warranted (Table 1). If the risks are acceptable to the woman and her physician, therapy of as short a duration as possible, and at as low a dose as possible, may be indicated.[15–18]
- While scientific debate and subanalysis of existing data continue, the available evidence indicates that specific adverse outcomes may occur at different times after initiation of HRT. For combined estrogen–progestin therapy, the risk of certain cardiovascular events would appear to increase soon after therapy is begun, within the first few months for coronary artery disease and venous thromboembolism and by about 18 months for stroke. The elevated risk for all 3 persists at least through the first 5 years of HRT. On the other hand, the risk for invasive breast cancer does not become elevated until later in therapy, around year 4. For estrogen-only therapy, the increased risk of stroke within the first year continues to increase throughout the 6.8 years of follow-up, whereas the slightly increased risk of coronary artery disease in the early follow-up period diminishes over time. This information may help women in deciding whether to initiate HRT for the relief of menopausal symptoms and, if initiated, in deciding how long to take it.

tom relief as well as a balance sheet of risks and benefits (Table 1).

Recommendations by others

The US Preventive Services Task Force,[15] the American College of Obstetricians and Gynecologists,[16] the North American Menopause Society (NAMS),[17] Health Canada,[18] the US Food and Drug Administration (FDA)[19] and, in a joint statement, the Heart and Stroke Foundation of Canada, the Society of Obstetricians and Gynaecologists of Canada and the Canadian Cardiovascular Society[20] all have recommended that asymptomatic women should not use combination estrogen–progestin therapy for the prevention of cardiovascular disease or other chronic diseases, because the risks outweigh the benefits. They advocate that women considering HRT should discuss their individual risks with their physician. These groups also recommend that women who choose to take HRT to relieve menopausal symptoms should use as low a dose as possible and for as short a time as possible, with periodic re-evaluation of whether HRT is still required. The FDA and NAMS have extended these recommendations to include all estrogen preparations, including unopposed estrogen. Their stance is that, until there is evidence from randomized controlled trials showing benefit, other methods of lowering cardiovascular disease and cancer risk (e.g., smoking cessation, and lifestyle and diet changes) should be used.

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