Demystifying menopausal hormone therapy prescribing

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Background
Menopause and perimenopause are associated with vasomotor symptoms and other symptoms that can affect quality of life. Menopausal hormone therapy (MHT) improves menopausal symptoms and reduces the risk of osteoporosis and fracture.

Objective
This article provides an updated overview of the basic principles of prescribing MHT, including the risks and benefits and practical information for tailoring treatment to the individual.

Discussion
Women presenting at menopause should have a comprehensive assessment including updated health screening and promotion of a healthy lifestyle. MHT can be offered to women with symptoms in the absence of contraindications, following a discussion about risks and benefits. MHT comprises systemic oestrogen, and for those with an intact uterus, a progestogen.

MENOPAUSE REFERS TO the final menstrual period, or more accurately the final cessation of ovarian function, and occurs at an average age of 51 years for Australian women. Perimenopause usually commences with the onset of menstrual cycle changes and is associated with fluctuating ovarian function and hormone levels.[1] Box 1 lists definitions related to menopause. Menopause is usually spontaneous but can be caused by medical treatments including chemotherapy, radiotherapy or surgical removal of the ovaries. In this article, the term 'women' refers to cisgender women. Transgender and non-binary individuals might also have menopausal symptoms and can benefit from appropriately tailored health services.

Most women have symptoms at perimenopause and menopause, and for some women symptoms can have a profound effect on quality of life. Around 75% of women have vasomotor symptoms (VMS; hot flushes and night sweats), with about 28% of women reporting moderate to severely bothersome VMS.[2] Other symptoms include sleep disturbance, low mood, anxiety, musculoskeletal pain and cognitive concerns (often referred to as 'brain fog'). Genitourinary symptoms are common and include vaginal dryness, dyspareunia, urinary urge and frequency, and dysuria. Menopause is also associated with a reduction in bone mineral density and changes in cardiovascular risk factors such as increased central adiposity. Women should have a comprehensive assessment including exploration of symptoms, evaluation of cardiovascular and bone health and updated screening, along with promotion of healthy lifestyle. This is outlined in *A Practitioners Toolkit for Managing Menopause*,[3] which is an Accepted Clinical Resource (ACR) for

Box 1. Definitions related to menopause

Menopause: the final menstrual period or the permanent cessation of ovarian function

Early menopause: menopause occurring at age 40–44 years of age

Premature ovarian insufficiency: menopause occurring before 40 years of age; women might have oligoamenorrhoea or amenorrhoea during this time

Perimenopause: from when the menstrual cycle starts to change until 12 months after menopause

Postmenopause: from 12 months after menopause

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The Royal Australian College of General Practitioners (RACGP), as well as the article by Spencer and Newman,[4] also in this edition of the Journal.

The use of menopausal hormone therapy (MHT) plummeted after the initial publication of the Women's Health Initiative in 2002,[5] which reported a link between conjugated equine oestrogen with medroxyprogesterone acetate and breast cancer, heart disease, stroke and venous thromboembolism. Subsequent reanalyses of the data, along with other studies, have refined our understanding of the risks and benefits of MHT, particularly with regard to timing of initiation and types of formulations. MHT should be offered to women where there are appropriate clinical indications, after an individualised assessment.

What is MHT?

MHT is medication comprising systemic oestrogen, along with a progestogen if required, for the treatment of the symptoms or consequences of menopause. The oestrogen is usually delivered either orally or transdermally, and for those with an intact uterus, a progestogen is also prescribed to prevent endometrial hyperplasia.

MHT is also known as hormone replacement therapy (HRT), but MHT is the preferred term, except for women with premature ovarian insufficiency (POI) or early menopause, when HRT is more accurate.

Clinical indications for MHT

The recognised indications for MHT are for the management of menopausal symptoms, including genitourinary symptoms, and for the prevention or management of low bone density and osteoporosis. It is also recommended that women with POI take HRT until the usual age of menopause. In addition, HRT is also generally recommended for women aged 40–45 years with early menopause.

The manifestations of menopause vary considerably from one woman to another and the decision to use MHT is based on an individual's risk versus benefit profile. Hot flushes and sweats are the cardinal symptoms and are highly responsive to treatment with MHT. Other commonly reported symptoms include sleep disturbance, low mood or anxiety and low libido. Cognitive symptoms, often described as 'brain fog', are common during perimenopause. However, although MHT might assist by relieving vasomotor symptoms and sleep disturbance, there is limited evidence for MHT directly alleviating cognitive symptoms.[6,7]

Oestrogen exerts antiresorptive effect directly by inhibiting osteoclast differentiation[8] and function.[9] In the Women's Health Initiative study, combined oestrogen and progestogen reduced the risk of total fractures by 24% and hip fractures by 34% compared with placebo.[10] MHT can be prescribed for management of low bone density or osteoporosis, particularly for women more recently menopausal, including women without vasomotor symptoms.[11,12]

When can MHT be commenced?

Women can be offered MHT if they present with relevant indications and it is not necessary to wait until after menopause has occurred. Guidelines often recommend that MHT be commenced within 10 years of menopause or under the age of 60 years because it is considered that benefits are more likely to outweigh risks if started early.[13] However, it is increasingly recognised that restricting the initiation of MHT to women younger than 60 years or within 10 years of menopause might be unnecessarily cautious.[14] If commencing MHT over the age of 60 years, low dose transdermal oestradiol might be a safer option.[15]

Contraindications and precautions for MHT are listed in Box 2.

Risks of MHT

Much of the information pertaining to the quoted risks of hormone therapy is derived from the Women's Health Initiative (WHI) study.[5] While the WHI study included large randomised controlled trials, there are recognised limitations, including that the women were not representative of typical users of MHT.[16] Women were older and few of them had vasomotor symptoms.[16] Furthermore, the types of hormones used (conjugated equine oestrogen and medroxyprogesterone acetate) are rarely used in the modern era.

Breast cancer

The risk of breast cancer should be discussed with all women commencing MHT. The WHI trial and large observational studies found a small increase in breast cancer risk for women using combined MHT.[5,17]

The risk of breast cancer increases with longer duration of use[17,18] and might be

Box 2. Contraindications to menopausal hormone therapy

Contraindications:

- Breast cancer and other hormone dependent malignancies
- Undiagnosed vaginal bleeding
- Acute cardiovascular events (myocardial infarction or stroke)
- Severe liver disease
- Active venous thromboembolism
- Porphyria cutanea tarda

Conditions where caution is recommended and transdermal oestrogen is advised:[3,15,42]

- Migraine with aura
- Past myocardial infarction, transient ischaemic attack or stroke
- Past venous thromboembolism or increased risk for venous thromboembolism
- Liver or gallbladder disease
- Hypertriglyceridaemia
- Age over 60 years and no prior menopause hormone therapy

Individual assessment and liaison with other specialists:

- Increased risk of breast cancer (eg women at moderate or high risk of breast cancer on risk calculators, and women with high breast density)

influenced by the type of progestogen. Micronised progesterone (and the structurally similar dydrogesterone) is associated with a lower risk of breast cancer than other progestogens in observational studies,[17,19,20] but there are insufficient long-term data to infer that they confer no risk with long term use.

The risk of breast cancer with oestrogen-only therapy seems less clear. The WHI study showed a reduction in breast cancer risk,[16] while other large studies, mainly observational, suggest a slight increased risk.[18,20] Overall, data indicate oestrogen-only therapy to be associated with a lower risk of breast cancer than combined oestrogen and progestogen therapy.

Tools that assess breast cancer risk, such as iPrevent[21] (Peter MacCallum Cancer Centre, Melbourne, Vic), might be helpful for clinicians to use during consultations. Information for patients on MHT and breast cancer risk is available from the Australasian Menopause Society.[22]

Coronary heart disease

Initial reports from the WHI trials reported an increase in adverse coronary heart disease (CHD) events in women taking continuous combined MHT compared with placebo.[23] Subsequent analyses stratified to age showed no increased risk in women aged 50–59 years and for those who commenced MHT within 10 years of their menopause.[24] Similarly, a Cochrane analysis of 19 studies found that women who commenced hormone therapy less than 10 years after the menopause had lower mortality and coronary heart disease than non-users.[25]

MHT therefore appears to be safer when initiated closer to the menopause. One approach might be to determine an individual's cardiovascular risk with a risk calculator, such as the AusCVDRisk calculator (Australian Chronic Disease Prevention Alliance, Australia) from the Heart Foundation Australia (www.cvdcheck.org.au). Those at high risk may be counselled to use low dose transdermal therapy with micronised progesterone or non-hormonal options.

It is currently not recommended that MHT be prescribed for the primary prevention of cardiovascular disease,[26] with the exception being women with premature menopause.[27]

Venous thromboembolism

Oral oestrogens undergo first-pass metabolism in the liver, increasing coagulation factors, and are associated with an increase in risk of venous thromboembolism (VTE). Data largely from observational studies consistently suggest transdermal oestradiol confers little or no VTE risk above baseline and is the preferred option for women with risk factors for VTE.[28,29] For women at low baseline risk, the absolute risk remains low and oral oestrogen might be a suitable option. The type of progestogen might also influence VTE risk; micronised progesterone does not appear to increase the risk.[30]

Stroke

The risk of stroke depends on the timing of initiation and the type of therapy. Commencing oral MHT for those aged over 60 years, there is an increase in stroke risk compared with non-users.[25] Transdermal oestrogen patches at doses of ≤50 mcg was not associated with increased rate of stroke in women aged 50–79 years in one nested case control study.[31]

How to prescribe MHT

Oestrogen

Oestrogen can be transdermal or oral and should be commenced at low to medium dose. Transdermal oestradiol is generally considered to be the first line option for most women,[15] and is available as a gel or patch. Two gel formulations are available in Australia. One (Estrogel) is a pump pack of gel, which is applied to a large surface area of the arm or thigh, with one pump daily being low dose, and two pumps daily being medium dose. The other gel formulation (Sandrena) is available in sachets and the gel is applied daily to the lower trunk or thigh to an area one or two times the size of the hand, with low and medium dose sachets available. Patches (Estradot, Estraderm MX and Estramon, available in various doses) are applied to the lower abdomen or buttock and changed twice weekly. If the woman has had a total hysterectomy a progestogen is not required, except where there has been extensive endometriosis, where a progestogen is usually recommended.[32]

Addition of progestogen

For women with an intact uterus a progestogen is required.[26,33] For women who are perimenopausal, the progestogen is generally taken in a cyclic fashion, usually 12–14 days per month. Together with oestrogen this is known as cyclic or sequential MHT. For women who are postmenopausal, the progestogen is used continuously. This is known as continuous combined MHT. It is important to ensure that the dose of progestogen is adequate and that the importance of the progestogen for endometrial protection is explained to the patient to encourage adherence.

The choice of progestogen depends on a range of factors including contraceptive requirements, the need to manage menstrual cycles, side effect profile and risks. Micronised progesterone (Prometrium), and the structurally similar dydrogesterone (available in Femoston), might have advantages over synthetic progestogens in terms of metabolic and breast cancer risks and is often a preferred first-line option.[15] Micronised progesterone can be used in a dose of 200 mg for 12–14 days per month for cyclic MHT and 100 mg daily for continuous use. It is usually taken at night because it can have a sedative effect.

A levonorgestrel 52 mg intrauterine device (IUD) (Mirena) might be used as the progestogen component of MHT and has the potential additional benefits of providing contraception and reducing menstrual bleeding. It is approved for contraceptive use for 8 years, but if used for endometrial protection it should be changed after 5 years of use.

Tibolone

Tibolone (Livial, Livilan, Xyvion and generics) is a synthetic compound that when metabolised, has oestrogenic, progestogenic and androgenic actions. It is indicated for women who are postmenopausal with symptoms of the menopause or low bone density. The androgenic component might benefit women with low libido. Caution is advised for women over 60 years as trials showed an increase in stroke risk in this group.[34]

Use of the combined oral contraceptive pill

For eligible women under 50 years, the use of the combined oral contraceptive pill (COCP)

might be appropriate. It provides cycle control, contraception and in many cases relieves menopausal symptoms. An oestradiol or estetrol containing pill might be preferable to those containing ethinylestradiol, and taking continuous hormone pills (by omitting the inactive pills) should be considered.[3] Examples include the formulation containing estradiol and nomegestrol (Zoely), and the formulation containing estetrol and drospirenone (Nextellis).

Counselling about adverse effects

All patients should be counselled about both initial side effects and longer-term risks of MHT. MHT can be associated with side effects. Although these are usually classified as 'minor', they might be troublesome and necessitate a change in dose or formulation. Common side effects include breast tenderness, headache and bloating, which can often settle quickly. Uncommonly, progestogens can cause an adverse effect on mood. Irregular bleeding or spotting can be common in the first weeks or months of treatment. Any unscheduled bleeding after the first 6 months of therapy should be investigated.[3] Although weight gain is common during the menopause transition years, MHT does not cause weight gain.[35]

Management of perimenopause

For many women symptoms start during perimenopause. If prescribing MHT during perimenopause, there are several considerations that might influence choice of therapy. The need for contraception should be considered. For women with heavy or irregular bleeding, careful assessment is required, and any necessary investigations should be completed prior to commencing MHT. Some women have worsening of premenstrual syndrome (PMS) or premenstrual dysphoric disorder (PMDD) during perimenopause, and this might also influence treatment choices.

The COCP or levonorgestrel IUD might be suitable options during perimenopause when control of the cycle, bleeding or contraception are required. Sequential MHT can be used, but in some cases is associated with irregular bleeding. The use of the 4 mg drospirenone contraceptive pill (Slinda) along with transdermal oestrogen might be an option when oral oestrogen is contraindicated, for example for women with migraine with aura. This combination is 'off-label' in Australia.[3,36]

Some women present with a range of symptoms while they are still having regular periods and are not yet perimenopausal according to internationally agreed definitions.[1] Clinicians should assess patients thoroughly and consider alternative diagnoses including PMS and PMDD. MHT prescription for women with regular periods is generally not recommended in guidelines, but if a trial of treatment is considered, a shared decision-making approach should occur, including discussion about the lack of evidence guiding practice.

Custom compounded hormone therapy

Compounded 'bio-identical' hormone therapy has been promoted as a way of offering personalised 'natural' therapy with low or no risks, for example, including troches containing a variety of hormones including oestrogens, progesterone and androgens. However, the prescription of compounded bio-identicals is not advised because of a lack of evidence of efficacy and safety for this approach.[37] The term 'body-identical' is sometimes used for regulated pharmaceutical products that contain hormones that are structurally the same as that produced by the human body. This includes oestradiol, micronised progesterone and testosterone.

Follow up and monitoring

When MHT is prescribed, a follow-up consultation should be arranged, typically in 6–12 weeks. Efficacy can be assessed, along with any adverse effects. A symptom score can be helpful in monitoring progress and therapy can be adjusted if needed. If symptoms are not adequately managed, an increase in oestrogen dose can be considered. The dose of progestogen might also need to be increased to ensure endometrial safety. The Australasian Menopause Society website lists MHT products available in Australia, with guidance on dosage.[38]

Some practitioners advocate monitoring of oestradiol and other hormone levels to attempt tailoring MHT to the individual. An oestradiol level might be helpful to assess absorption of transdermal oestradiol in a patient on higher doses of transdermal oestradiol who has residual symptoms, but routine monitoring is not recommended. A treatment target range for oestradiol levels has not been established, and serum oestradiol levels might not reflect hormone activity at a cellular level. Current guidance is that symptoms are the best guide to treatment, and that oestrogen should not be prescribed above the maximum registered doses without non-general practitioner (GP) specialist involvement.[15]

Duration of treatment

Once treatment has been established, yearly review is recommended. At this time, the indications for MHT and the need for ongoing treatment should be reviewed, along with the risks and benefits, as they apply to the individual. A trial of lower dose or cessation can occur if the need for treatment is uncertain. There is no arbitrary duration for use of MHT and previous advice to restrict use to 5 years or to stop MHT when a woman reaches age 60 years is no longer appropriate, particularly if the woman feels that there has been ongoing benefit.[6] Women should be counselled about breast cancer risk increasing with duration of use and a shared decision-making process should be used.

Testosterone

Testosterone (AndroFeme 1, transdermal cream) is commonly promoted as an option to improve mood or energy levels. However, the only evidence-based indication for testosterone is for hypoactive sexual desire disorder in women who are postmenopausal, and testosterone is not a routine component of MHT.[39]

Genitourinary symptoms

Unlike vasomotor symptoms, genitourinary symptoms are reported to worsen over time. Up to 27% of women on systemic MHT will describe ongoing symptoms.[40] Vaginal oestrogen is highly effective and should be offered either alone or in combination with systemic MHT. Options include vaginal oestradiol pessaries (Vagifem Low or Estro Pess) or estriol cream or pessaries (Ovestin). Vaginal DHEAS (dehydroepiandrosterone) (prasterone 6.5 mg, [Intrarosa]) is also effective, but there are no head-to-head studies comparing it to the various forms of vaginal oestrogen. The low dose topical hormonal treatments do not require the

addition of a progestogen. Vaginal oestrogen might be an option for women with a history of breast cancer, but discussion with the patient's cancer specialist should be considered.[41]

Conclusion

MHT is the recommended first-line treatment for menopausal symptoms and can be offered to women who do not have a contraindication. For most women, MHT is safe and can greatly improve quality of life. There should be a discussion about risks and benefits, individually tailored treatment and appropriate follow-up.

Key points

- MHT is the most effective treatment for the relief of menopausal symptoms.
- MHT reduces fracture risk and can be prescribed for the prevention or management of low bone density.
- Before prescribing MHT, a thorough assessment and discussion about the risks and benefits should be conducted with the patient.
- Oestrogen should commence at low to medium doses and must be accompanied by a progestogen unless the woman has had a total hysterectomy.
- Once MHT is prescribed it should be reviewed and, if necessary, adjusted to manage efficacy and side effects.

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