NICE – How safe is HRT?

Dr Louise R Newson examines the recent NICE guidelines and considers the implications for prescribing hormone replacement therapy

Menopause is a normal life event for women and not an illness or a medical condition. However, over the last century our life expectancy has increased hugely. This has resulted in many more women being affected by symptoms of their menopause, often to the detriment of their families, work and life in general. Many women suffer in silence and do not realise how effective hormone replacement therapy (HRT) can be in improving their symptoms and quality of life.

On average, women spend nearly a third of their life being postmenopausal. The retirement age is increasing and elderly people are far more active, physically and mentally, than they were in the past.

The NICE guidelines on menopause were published last November and should be encouraging for many doctors. These are the first clinical guidelines on menopause and provide clear recommendations on the diagnosis and treatment of women with menopausal symptoms.

The prescribing of HRT has long been controversial. Over the past decade, a vast number of clinicians have become reluctant to offer HRT to women, resulting in large numbers of women missing out on the benefits of HRT. In addition, many women have been unnecessarily worried about the perceived risks of HRT and so have avoided talking about their symptoms and asking their doctors for help.

Around 80% of women going through their menopause experience symptoms, but only a small proportion of menopausal women take HRT; in some parts of the UK only 15% of menopausal women take HRT. Symptoms of the menopause last far longer than most women anticipate; the average length of time is four years and many women still have symptoms after 8-10 years.

So what do the NICE guidelines teach us? They empower us with more knowledge and confidence to diagnose and manage the menopause. They provide clear statements regarding benefits and risks of HRT. Importantly, there is also a section on diagnosing and managing premature ovarian insufficiency.

When discussing menopause with women, it is important they receive individualised care. They should receive appropriate information, allowing them to make informed choices regarding the treatment they receive.

Making a diagnosis of menopause

NICE is very clear regarding making a diagnosis of the menopause. In women over 45 years with menopausal symptoms or presenting with amenorrhea over 12 months, investigations are now no longer necessary. In those women aged under 45 years, FSH may be used to diagnose the menopause. Other tests are largely unnecessary. This means that women can start treatment sooner, which will be advantageous for many women, especially those with more severe symptoms.

Treatment

For the majority of menopausal women with vasomotor symptoms, HRT remains the treatment of choice. The choice of preparation varies according to the individual woman, their medical history and their personal choice.

Alternative treatments, such as selective serotonin reuptake inhibitors or clonidine, should not be given. There is poor evidence regarding other products, such as isoflavones, black cohosh or bioidentical hormones, and the safety of many of these products is uncertain.

Testosterone is still not licensed for use in women in the UK. However, it does have a role for those women who still have low libido despite receiving HRT.

Other symptoms of the menopause

Many clinicians and women understand the benefits of HRT regarding the classical symptoms of the menopause – hot sweats, flushing, tiredness – but may not be confident with less classical presentations.

I have seen numerous women over the years who present in their late 40s and early 50s with symptoms of depression and low mood. In the past I have considered giving these women antidepressants, but as my interest in the menopause has increased I am now far more direct about asking them about other menopausal symptoms. The vast majority of these women have irregular (or no) periods and also have other symptoms of the menopause but do not think them important to mention to a doctor.

It is often really satisfying to give these women HRT after a full discussion regarding the benefits and risk and learning from the review that they feel so much better. NICE clearly states we should be considering HRT to alleviate low mood that arises as a result of the menopause.

Some women present during or after their menopause with symptoms of urogenital atrophy; one of the most common symptoms is recurrent urinary tract infection with negative MSUs. These symptoms are often effectively managed by giving women topical vaginal oestrogen. It is a pity that many doctors have not been keen on these preparations being prescribed as a repeat prescription, which often results in women returning with troublesome symptoms once they have run out of their treatment.

These doctors will hopefully be now reassured with the recent guidance that states vaginal oestrogen should be offered to women (including those on systemic HRT) and then continued for as long as needed to relieve symptoms. The only real contra-indication to these preparations is active breast cancer. After all, a year's supply of topical oestrogen is equivalent to having one tablet of HRT.

Benefits and risks

There is not enough room to list all the benefits and risks in this editorial, so I will focus on just some.

HRT works really well at improving vasomotor symptoms and reduced libido, and many women notice their skin, hair, joints and well being improve too.

Osteoporosis is often referred to as a "silent killer"; in the UK around 1,100 people die each month after fracturing their hip, so far more people than from breast cancer.[1] Treatments for osteoporosis are limited and are not without side effects or risks. In addition, hip fractures are costing the NHS around £2.3 billion each year.

Bisphosphonates are not as safe as we thought when they were first launched and the evidence regarding their efficacy at reducing fractures is still limited. Oestrogens are the most effective way of increasing bone mineral density and also preventing osteoporotic fractures in women. In women under 60 years, they should be given as first line treatment for the management of osteoporosis. HRT is of most benefit as primary prevention when started early in menopause.

In the past there has been concern about the association of cardiovascular disease (CVD) and HRT. Historically, studies started women on HRT when they were over 60 years of age, and in some cases women were given high doses of oral HRT. More recent studies have looked at starting HRT after the menopause, as this seems to be important with respect to CVD risk. Giving HRT to women early (less than 10 years since the menopause) has been shown to have a significant reduction in all cause of death and a 50% reduction in risk of death from coronary heart disease. For secondary prevention there is no increased risk of myocardial infarction or death (either all-cause or from CVD causes).

NICE has been cautious in their recommendations but have stated that HRT with oestrogen alone is associated with no, or reduced, risk of coronary heart disease and HRT with oestrogen and progestogen is associated with little or no increase in the risk of coronary heart disease. In addition, it is important to note that the presence of cardiovascular risk factors is not a contra-indication to HRT, as long as they are optimally managed.

Regarding stroke risk in women taking HRT, there is no evidence that using transdermal HRT increases the risk of stroke, although there is a low risk of stroke in women taking oral HRT. The baseline population risk of stroke in women aged under 60 years old is low, however, and women should be made aware of this.

The risk of venous thromboembolism (VTE) in women using transdermal HRT is not increased. There is an increased risk of VTE in those taking oral oestrogen; the risk is approximately double. It is worth remembering that this increased risk is far lower than that experienced when taking the combined oral contraceptive pill or with pregnancy. The background risk of VTE rises with increasing age.

When women are asked about reasons not to take HRT, the most common answer is concerns about the increased risk of breast cancer. Results of studies show that, at worst, an extra four women per 1,000 might get breast cancer by taking HRT. Other studies have failed to demonstrate any increased risk of breast cancer with HRT. An important learning point is that taking HRT does not affect the risk of dying from breast cancer. Women need to be made aware that this increased risk is similar to being overweight or having a glass or two of wine each night. This often helps to put the risk into perspective.

Premature ovarian insufficiency

Finally, NICE is clear regarding the need for women who have premature ovarian insufficiency to receive HRT until the average age of the menopause. I often see women in their 40s suffering with horrendous menopausal symptoms and discover their HRT has been stopped by another doctor. Any risks of HRT are not applicable – risks are only relevant to women over 50 years old.

Without receiving oestrogen this means their lives have often been miserable and they now face a greater risk of osteoporosis, cardiovascular disease and depression. We all should have a lower threshold for asking women when their last period was and then acting appropriately.

These NICE guidelines enable clinicians to feel more confident in offering HRT to eligible women. They should also help women to make a more informed choice regarding their treatment, which can now be based on a more balanced review of the evidence. HRT is generally a safe, effective treatment of the menopause and should be considered for many more women than it has been in the recent past.

References

1. http://www.thebms.org.uk/publicdownloads/Osteo_Report2010.PDF (last accessed 6 January 2016)