NICE National Institute for Health and Care Excellence

NICE guidance

Removal, preservation and subsequent reimplantation of ovarian tissue to prevent symptoms from the menopause

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

1.1 Evidence on the safety and efficacy of removal, preservation and subsequent reimplantation of ovarian tissue to prevent symptoms from the menopause is inadequate in quality and quantity. Therefore, this procedure should not be done unless it is part of a formal research study, with appropriate governance and ethics approval. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Research should include randomised controlled trials and should report details of:

- patient selection, including the age at which ovarian tissue is removed
- the procedure, including the techniques used for harvesting tissue and cryopreservation, the timing and the frequency of reimplantation of ovarian tissue, and the association between the amount of tissue removed and reimplanted and subsequent endocrine function
- endocrine function in the period between removing and reimplanting ovarian tissue
- a comparator group who have pharmacological hormone replacement therapy (HRT).

1.3 Patient selection should be done by a multidisciplinary team including clinicians with specialist expertise in managing menopause.

1.4 The procedure should only be done by surgeons with specialist expertise in the procedure.

2 The condition, current treatments and procedure

The condition

2.1 Menopause occurs with the final menstrual period and is usually diagnosed clinically after 12 months of amenorrhoea. It usually happens when someone is between 45 and 55, although around 1% of women have early (premature) menopause before 40.

2.2 As oestrogen levels reduce, most people have some symptoms, which can affect quality of life. Most commonly, these are hot flushes and night sweats. Other symptoms are mood changes, memory and concentration loss, vaginal dryness, a lack of interest in sex, headaches, and joint and muscle stiffness. Menopause can also increase the risk of osteoporosis and cardiovascular disease.

Current treatments

2.3 Symptoms can be treated with pharmacological hormone replacement therapy (HRT). For someone with a uterus, HRT usually consists of an oestrogen and a progestogen. For someone who has had their uterus removed, it is usually oestrogen only. HRT aims to replace the hormones that are no longer produced by the ovaries because of menopause. Non-hormonal treatments can also be used.

The procedure

2.4 The level of reproductive hormones and ovarian reserve is assessed first. If this is adequate, one-third to one-half of the outer cortex of 1 ovary is removed laparoscopically under general anaesthesia and cryopreserved in thin slices. When menopause starts, a slice of the ovarian tissue is

thawed and regrafted under the skin in a heterotopic site (for example, the forearm or axilla) with the aim of restoring normal ovarian endocrine function. The transplantation process is reversible and may be repeated to maintain endocrine function. The aim is to prevent the symptoms associated with the menopause.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This rapid review did not identify any relevant studies.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: quality of life outcomes including menopause-specific questionnaires and endocrine function of the implant (including the levels of oestrogen, progesterone and follicle stimulating hormone) in the short and long term.

3.3 The professional experts and the committee considered the key safety outcomes to be: laparoscopy-related complications (including pain, bleeding and infection), reduced fertility (in the period between ovarian tissue removal and reimplantation), and premature menopause.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee was informed that the same procedure can be used to preserve fertility or to prevent menopausal symptoms or premature menopause from iatrogenic (such as cancer treatment) or non-iatrogenic (such as hereditary or disease) causes. This guidance is specifically for its use to prevent menopause symptoms in otherwise healthy people and does not cover these other indications.

3.6 The committee was informed that although published evidence for the use of this procedure for fertility preservation for medical reasons exists, there was no published evidence for its use in otherwise healthy people who wanted to prevent menopause symptoms. This underpinned the committee's recommendation for research to be done to establish its safety and efficacy.

3.7 The committee was informed that pharmacological hormone replacement therapy (HRT) has an established efficacy and safety profile for preventing the symptoms of menopause.

3.8 The committee was informed that there is a small risk of significant complications associated with laparoscopy.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation