NICE National Institute for Health and Care Excellence

NICE guidance

Endometrial cryotherapy for menorrhagia

HealthTech guidance
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www.nice.org.uk/guidance/htg101

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.

Contents

This guidance replaces IPG157.

1 Recommendations

1.1 Limited short-term evidence on the safety and efficacy of endometrial cryotherapy for menorrhagia appears adequate to support the use of this procedure in carefully selected patients provided that normal arrangements are in place for consent, audit and clinical governance.

1.2 Clinicians should ensure that patients understand that there are alternative treatment options with different likelihoods of achieving complete amenorrhea or normal periods. Appropriate patient selection and patient choice are both important. In addition, use of NICE's information for the public is recommended.

2 The procedure

2.1 Indications

2.1.1 Menorrhagia is heavy cyclical menstrual bleeding over several consecutive cycles in a woman of reproductive years. Menorrhagia is clinically defined as a total menstrual blood loss of more than 80 ml per menstruation.

2.1.2 Menorrhagia has adverse implications for quality of life. Women with menorrhagia may have difficulties with daily activities such as work, family life and social activities. Many women report anxiety, depression, embarrassment and problems in their sex lives as a result of menorrhagia. Anaemia is also common among women with menorrhagia, and this may further impair quality of life.

2.1.3 Patients are usually treated with medication before surgery is considered. This may be administered orally or released into the lining of the uterus (endometrium) by a special intrauterine device. Historically, hysterectomy has been the standard surgical option for women with menorrhagia who no longer desire to maintain fertility. Alternatives to hysterectomy are minimally invasive procedures that may be performed using a hysteroscope. These include transcervical endometrial resection or destruction of the endometrium with lasers, electrocautery, radiofrequency waves or heated saline. Non-hysteroscopic procedures include destroying the endometrium using heated saline, heated balloons, lasers, radiofrequency waves or microwaves. Non-hysteroscopic procedures are often carried out under local anaesthesia as a day admission.

2.2 Outline of the procedure

2.2.1 Endometrial cryotherapy is a non-hysteroscopic procedure that uses cold temperatures to freeze and destroy the endometrium. It can be performed under general, regional or local anaesthesia, although sometimes no anaesthesia is needed. A cryoprobe is inserted into the fundus of the uterus and cooled by perfusing it with either liquid nitrogen or a compressed gas mixture. The tip of the

probe is placed first in one cornu of the uterus and then in the other, to generate an iceball that destroys the endometrial tissue. Each freeze cycle is followed by a heat (thaw) cycle, which allows the probe to be removed. Additional freeze and thaw cycles may be carried out if necessary.

2.3 Efficacy

2.3.1 In a randomised controlled trial (RCT), rates of treatment success as assessed by the reduction of menstrual bleeding to a pictorial blood loss assessment chart (PBAC) score of 75 or less in the absence of retreatment at 12 months were 67% (130 out of 193 patients) and 73% (63 out of 86 patients) in the cryotherapy and electroablation groups, respectively. The proportion of patients in the cryotherapy and electroablation groups at 12 months (not analysed by intention to treat) with menorrhagia (PBAC greater than 100) were 12.2% and 6.9%, respectively, and with amenorrhoea (PBAC score 0) were 27.6% and 55.6%, respectively. In a case series of 67 women, none were amenorrhoeic during more than 3 months of follow-up (up to 18 months).

2.3.2 Patient satisfaction ranged from 67% (22 out of 33) at up to 18 months' follow-up in the case series, to 91% at 24 months in the RCT.

2.3.3 Retreatment at 24 months was reported for 10% (18 out of 186) of patients who had cryotherapy in the RCT: 7% (13 out of 186) of patients had a hysterectomy and 3% (5 out of 186) of patients had repeat cryoablation. For more details, refer to the overview.

2.3.4 The Specialist Advisors stated that the evidence from RCTs is limited, and that this procedure was one of a number of ablation techniques that uses different energy.

2.4 Safety

2.4.1 In the RCT, uterine perforation occurred during sounding before treatment in 0.5% (1 out of 186) of patients, and there were three serious adverse events that

occurred more than 15 days after the procedure (and within 12 months). These were severe abdominal cramping (two patients) and severe vaginal bleeding (one patient). Other adverse events reported at up to 12 months' follow-up included: abdominal or pelvic pain or cramping in 14% (26 out of 186) of patients; uterine cramping in 4% (7 out of 186); vaginal infection in 4% (7 out of 186); hot flushes in 2% (3 out of 186); urinary tract infection in 1% (2 out of 186); and nausea and vomiting in 0.5% (1 out of 186).

2.4.2 In the prospective case series of 67 women, adverse events reported immediately after the procedure included urinary frequency or urgency (100%), moderate pelvic pain, dysuria and vaginal discharge (the numbers of patients were not well reported). Other less commonly reported adverse events were prolonged tiredness and perimenopausal symptoms.

2.4.3 The adverse events reported in the US Food and Drug Administration Center for Devices and Radiological Health MAUDE database included excessive bleeding, uterine perforation bowel injury and stenosis of the cervix. For more details, refer to the overview.

2.4.4 The Specialist Advisors stated that the procedure appears to be safe, but there are no data available on the incidence of major complications. The theoretical adverse events include thermal injury to the cervix and vagina. Anecdotal adverse events include persistent discharge and endometritis.

2.5 Other comments

2.5.1 The committee noted that there are no long-term follow-up data.

3 Further information

Sources of evidence

The evidence considered by the committee is in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 157 has been migrated to HealthTech guidance 101. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.