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Endometrial cryotherapy for menorrhagia

Understanding NICE guidance –
information for people considering
the procedure, and for the public

Ordering information

You can download the following documents from www.nice.org.uk/IPG157

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0990 (full guidance)
- N0991 (information for the public).

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called endometrial cryotherapy for menorrhagia. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether endometrial cryotherapy is safe enough and works well enough for it to be used routinely for the treatment of menorrhagia (consistently heavy periods).

To produce this guidance, NICE has:

- looked at the results of studies on the safety of endometrial cryotherapy for menorrhagia and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

Menorrhagia is the medical name for heavy periods – it's usually taken to mean heavy bleeding over several consecutive periods. Usually, women are offered medication before surgery becomes an option. In the past, hysterectomy (removal of the womb) has been the standard operation, but there are now alternatives that use what's known as a minimally invasive approach. These procedures are carried out using equipment that's passed into the womb through the vagina. The aims are to cause less damage to the area than standard surgery, to make side effects less likely and to allow the woman to recover more quickly.

Endometrial cryotherapy is a minimally invasive procedure that involves using cold temperatures to freeze and destroy the lining of the womb (this lining is called the endometrium). A probe is gently inserted into the womb and this is then cooled by passing liquid nitrogen or a liquid gas mixture into it. The cooled probe is used to form a ball of ice, which is passed over the endometrium to freeze it. Once this is complete, the probe is thawed and removed. The freeze/thaw cycle can be repeated if necessary.

How well the procedure works

What the studies said

One study found that the cryotherapy procedure was as successful at lightening women's periods as another minimally invasive procedure called electroablation when the results were assessed 12 months after surgery. (Electroablation involves destroying the endometrium using heat.) In the group who'd had cryotherapy, 12% still had heavy periods, and in the group who'd had electroablation, 7% still had heavy bleeding. (12% is the same as saying 12 out of 100 women.)

Just over one-quarter of the women who'd had cryotherapy stopped bleeding altogether afterwards compared with just over one-half of those who'd had electroablation. Around 2 years after having the cryotherapy procedure, nearly all the women who'd had it (91%) were satisfied with the results. Eighteen out of the 186 women who had cryotherapy in this study needed further surgery within 2 years: 13 women went on to have a hysterectomy and 5 women had more cryotherapy.

In a second study, which followed what happened in 67 women who had cryotherapy, none of the women stopped bleeding altogether in the months after surgery (some women's progress was followed for up to 18 months). Two-thirds of women were satisfied with the results of the procedure in this study.

What the experts said

The experts commented that there hadn't been many good-quality studies carried out on endometrial cryotherapy. They also said that this was one of several procedures used to destroy the endometrium, although different procedures use different ways of doing it.

Risks and possible problems with the procedure

What the studies said

In one study, the uterus was damaged in the first stages of the procedure in 1 out of 186 women. Two women had severe abdominal cramping and one woman had severe vaginal bleeding. Other problems that affected women in this study in the 12 months after the procedure were: abdominal or pelvic pain or cramping (which affected 26 women); cramping in the abdomen (7 women); vaginal infection (7 women); hot flushes (3 women); urinary tract infection (2 women); and nausea and vomiting (1 woman).

The second study listed the problems women had immediately after the surgery (although it was not clear how many women were affected in some cases). All the women noticed that they had to urinate more often or felt an urgent need to urinate, some women had moderate pelvic pain, some found sex painful and some had vaginal discharge. A small number of women said they had prolonged tiredness and symptoms that would be expected around the time of the menopause.

In the USA, the Food and Drug Administration has recorded side effects of the procedure in its MAUDE database. These side effects include excessive bleeding, damage to the uterus and bowel, and narrowing of the cervix.

What the experts said

The experts said that the procedure appears to be safe, but there is no information on the likelihood of serious complications. In theory, the cervix and vagina could be damaged by the temperatures involved. Doctors have reported that some women have persistent discharge after the procedure and others have inflammation of the remains of the endometrium.

What has NICE decided?

NICE has considered the evidence on endometrial cryotherapy for heavy periods (menorrhagia). It has recommended that when doctors use this procedure for women with heavy periods, they should be sure that:

- the woman understands that alternative procedures are available, and that some are more likely than others to stop the bleeding altogether
- the woman understands what is involved and agrees (consents) to the cryotherapy procedure, and
- the results of the procedure are monitored.

NICE has also said that the procedure should only be offered to women who are likely to benefit from it.

Other comments from NICE

No studies have been carried out that have checked on the long-term health of women who've had endometrial cryotherapy.

What the decision means for you

Your doctor may have offered you endometrial cryotherapy for heavy periods. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of endometrial cryotherapy before you agree to it. Your doctor should discuss these with you, and should also describe the different procedures that are available and the likelihood of success with each type.

Further information

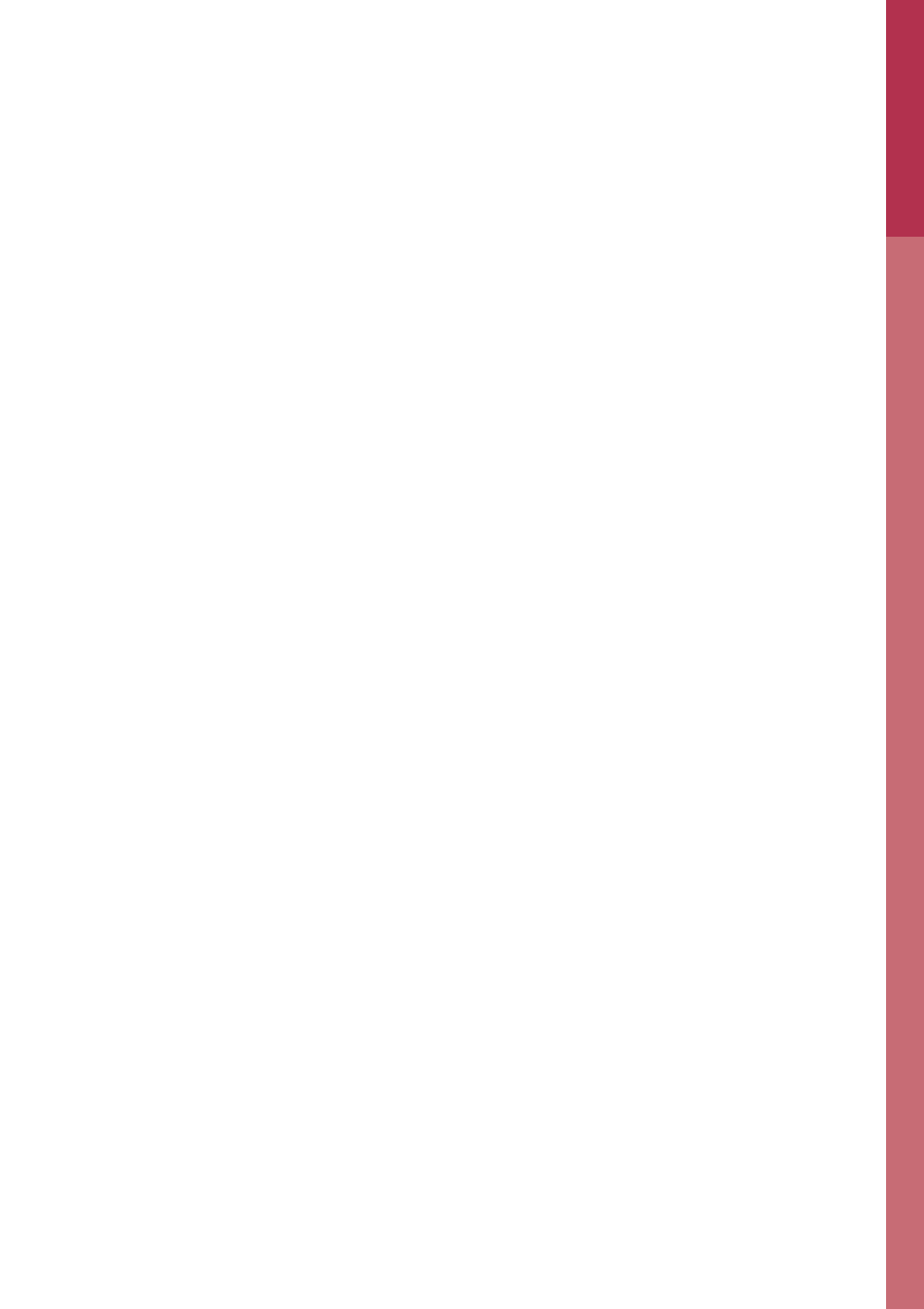
You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on endometrial cryotherapy for menorrhagia that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

NICE has issued guidance on the following minimally invasive procedures for heavy periods – for more information, either visit the NICE website or phone the NHS Response Line and ask for the information for the public, quoting the reference number listed: microwave endometrial ablation (www.nice.org.uk/IPG007 or reference number N0263), photodynamic endometrial ablation (www.nice.org.uk/IPG047 or reference number N0485), balloon thermal endometrial ablation (www.nice.org.uk/IPG006 or reference number N0257), free fluid thermal endometrial ablation (www.nice.org.uk/IPG051 or reference number N0497), and impedance-controlled endometrial ablation (www.nice.org.uk/IPG104 or reference number N0784).

If you have access to the internet, you can find more information on period problems on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.





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