Impedance-controlled bipolar radiofrequency ablation for menorrhagia

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

December 2004

Information from Interventional Procedure Guidance 104
Impedance-controlled bipolar radiofrequency ablation for menorrhagia

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

Issue date: December 2004

To order copies
Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0784. A version in Welsh and English is also available, reference number N0785. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0785. The NICE interventional procedures guidance on which this information is based is available from the NICE website (www.nice.org.uk). Copies can also be obtained from the NHS Response Line, reference number N0783.

National Institute for Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

Website: www.nice.org.uk


Published by the National Institute for Clinical Excellence
December 2004
Typeset by Icon Design, Eton
Print on demand

© National Institute for Clinical Excellence, December 2004. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes within the NHS. No reproduction by or for commercial organisations is allowed without the express written permission of the National Institute for Clinical Excellence.
Contents

About this information 4
About radiofrequency ablation for heavy periods 5
What has NICE decided? 8
What the decision means for you 9
Further information 10
About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called impedance-controlled bipolar radiofrequency ablation (for simplicity, it’ll be called radiofrequency ablation from here on). This information 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 radiofrequency ablation is safe enough and works well enough for it to be used routinely for the treatment of heavy periods (the medical word is menorrhagia).

To produce this guidance, NICE has:

• looked at the results of studies on the safety of radiofrequency ablation 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 radiofrequency ablation for heavy periods

During a period, the lining of the uterus (or womb) comes away and is passed through the vagina with some blood. In the interval before the next period, the lining grows again. If a woman is having heavy periods, one way of reducing the amount of blood and tissue lost is to remove some of the lining of the uterus, which is known as the endometrium.

In radiofrequency ablation, radiofrequency energy is used to heat and destroy the endometrial lining. The aim is to make the periods lighter or to stop them altogether (the medical word for this is amenorrhoea). The piece of equipment that delivers the radiofrequency energy is put into the woman’s vagina and passed up through her cervix and into the uterus. The equipment is designed so that, when it’s in place, the specific part that gives off the radiofrequency energy can expand to fit the shape of the uterus. After the heating has finished, the equipment is returned to its original shape and removed. For this procedure, the woman has either a local or a general anaesthetic.
How well it works

What the studies said

NICE looked at four studies of radiofrequency ablation for women with heavy periods. These showed that 1 year after having the treatment, around a half of the women were having no periods at all. The actual figures for this in the studies were 41% to 59% of women (41% being the same as saying 41 people in 100).

Two of the studies compared radiofrequency ablation with other methods of removing the endometrial lining. One of the other methods involved putting a small deflated balloon into the uterus then filling it with heated liquid. The other method involved using another type of equipment called a rollerball electrode to heat the endometrial lining. In both studies, more women stopped having periods after having radiofrequency ablation than after having the other method.

One study measured the reduction in bleeding in women after treatment. It looked at how many women went down to having normal periods or lighter after treatment (so this number included women who had spotting or no periods afterwards). The numbers for this were roughly the same in the group of women who had radiofrequency ablation and the group who had the rollerball method (91% and 88%).
Two studies found that women were generally satisfied with the radiofrequency treatment and that their quality of life was better after having the treatment. (The other two studies did not look at these things.)

**What the experts said**

The experts said that radiofrequency ablation seemed to work well in the short term, though not much was known about the long-term effects of the treatment.

**Risks and possible problems**

**What the studies said**

In the studies, some women had pelvic pain, inflammation of the endometrium, urine infection, nausea or vomiting after the treatment. In the study that included the most women, 23 out of 175 women had a problem after the treatment. Nine had urine or vaginal infections, two had a build up of blood in the uterus (this is known as a haematometra), and two women developed pelvic inflammatory disease.

**What the experts said**

The experts said that the possible problems were infection causing inflammation of the endometrial lining, bleeding, and damage to the uterus or surrounding area.
What has NICE decided?

NICE has considered the evidence on radiofrequency ablation for heavy periods. It has recommended that when doctors use it for women with heavy periods, they should be sure that:

• the patient understands what is involved and that there are uncertainties about the long-term effects of the procedure

• the patient agrees (consents) to the treatment, and

• the results of the procedure are monitored.

NICE has also encouraged doctors to keep records of how many women go back to having heavy periods some time after the treatment, and how many develop problems. This information will give a better picture of the long-term effects of radiofrequency ablation.

Doctors should also follow the recommendations of the Medical Devices Agency (MDA) when carrying out the procedure. (Since making these recommendations, the MDA has been replaced by the Medicines and Healthcare Products Regulatory Agency). The recommendations outline the circumstances where radiofrequency ablation might not be a suitable option. These are: if the woman has a small uterus; if a woman is taking hormone treatments before the procedure; and if the woman has had pelvic
infections in the past. The recommendations also say that if the doctor suspects that a woman’s uterus might have moved slightly from the usual position, he or she should check that the medical instruments are in the right place on an ultrasound scan before starting to heat the endometrium. And doctors are recommended to check, as routine, the uterus using a special viewing tube called a hysteroscope before putting the radiofrequency equipment into position. The MDA also recommended that diathermy, which uses a high-frequency electrical current to destroy the endometrium, should not be carried out at the same time as this treatment.

NICE has also said there’s a need to make sure doctors who want to carry out radiofrequency ablation are properly trained. The British Society for Gynaecological Endoscopy will be issuing training standards for doctors.

What the decision means for you

Your doctor may have offered you radiofrequency ablation 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 radiofrequency ablation and the uncertainties about its long-term effects before you agree to it. Your doctor should discuss these with you. Some of the benefits and risks may be described above.
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.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on impedance-controlled bipolar radiofrequency ablation for menorrhagia is on the NICE website (www.nice.org.uk/IPG104guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0783. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you want more information on period problems, a good starting point is NHS Direct, telephone 0845 4647, or NHS Direct Online (www.nhsdirect.nhs.uk).

Date: December 2004