

## Understanding NICE guidance

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Information for people who use NHS services

### Image-guided ultrasound treatment for uterine fibroids

*NICE 'interventional procedures guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.*

This leaflet is about when and how image-guided ultrasound can be used to treat women with uterine fibroids in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which women will benefit most from it.

This leaflet is written to help women who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe uterine fibroids or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

## What has NICE said?

There are still uncertainties over the safety of this procedure and how well it works. If a doctor wants to use image-guided ultrasound treatment for uterine fibroids, they should make sure that extra steps are taken to explain the uncertainty and the likely benefits and potential risks of the procedure. This should happen before the woman agrees (or doesn't agree) to the procedure. The woman should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens after the procedure.

## Other comments from NICE

Currently, there is no evidence on how well this procedure works as a treatment for impaired fertility caused by uterine fibroids.

*This procedure may not be the only possible treatment for uterine fibroids. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.*

## Image-guided ultrasound treatment for uterine fibroids

The procedure is not described in detail here – please talk to your specialist for a full description.

Uterine fibroids are common, non-cancerous growths in the womb that can sometimes cause heavy bleeding, pressure and pain in the abdomen. They may also cause reproductive problems such as infertility and miscarriage. After the menopause uterine fibroids usually become less troublesome and treatment is rarely needed.

Image-guided ultrasound treatment is a minimally invasive technique designed to reduce the symptoms of fibroids. During treatment, the woman lies on her front in a special machine that combines magnetic resonance imaging (MRI) with ultrasound. A fine tube (catheter) is placed in her bladder before the procedure begins. The fibroid can be seen by MRI. Low-power ultrasound is used to accurately target the fibroid, and it is then heated with high-power ultrasound which destroys the abnormal tissue. Throughout the treatment (which may last for 3 hours), the woman is able to let the operator know if she experiences any discomfort.

If symptoms do not improve following the procedure, a hysterectomy (removal of the womb) or myomectomy (removal of fibroids with open surgery) may be required.

## What does this mean for me?

If your doctor has offered you image-guided ultrasound treatment for uterine fibroids, they should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

### You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

## Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at five studies on this procedure.

### How well does the procedure work?

In two studies, 114 out of 160 women and 77 out of 109 women had a significant improvement in their symptoms 6 months after the procedure. In the first study, 76 women were still being followed after 1 year and 59 of them still had a significant improvement. In the second study, 82 women were still being followed after 1 year and approximately half of them still had a significant improvement.

In another study of 42 women, the procedure reduced menstrual bleeding from an average of 6.1 days to 4.9 days. The bleeding was also less heavy, with pads/tampons lasting an average of 30 minutes longer between changes during the heaviest flow.

*You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.*

In three studies, a significant number of women went on to have an additional treatment such as hysterectomy (23 out of 82, 11 out of 42 and 6 out of 49 women).

The expert advisers stated that improvement of symptoms is a good indicator of how well the procedure works. One adviser stated that there is a limited reduction in the size of fibroids following the procedure.

## Risks and possible problems

In the study of 160 women, 51% reported pain and discomfort.

In the study of 109 women, 5% had skin burns following the procedure, with 1 woman developing skin ulceration. In another study, 3 out of 49 women had skin burns, one of which was serious. In each of two studies (of 109 women and 42 women), 1 woman developed pain in the sciatic nerve (the nerve that runs down the leg), which resolved within 12 months in both women. Other reported complications included mild diarrhoea, fatigue and backache.

The expert advisers stated that skin burns and reversible nerve damage were the main potential complications of the procedure. They also commented that heat damage to nearby structures was possible in theory.

## More information about uterine fibroids

NHS Direct online ([www.nhsdirect.nhs.uk](http://www.nhsdirect.nhs.uk)) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

### About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Staff working in the NHS are expected to follow this guidance.

*To find out more about NICE, its work and how it reaches decisions, see [www.nice.org.uk/aboutguidance](http://www.nice.org.uk/aboutguidance)*

*This leaflet and the full guidance aimed at healthcare professionals are available at [www.nice.org.uk/IPG231](http://www.nice.org.uk/IPG231)*

*You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1338).*

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