

Treating severe obesity using keyhole surgery to stitch folds in the stomach to make it smaller

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This document is about when and how stitching folds in the stomach to make it smaller using keyhole surgery can be used in the NHS to treat people with severe obesity. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. 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.

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 patients will benefit most from it.

This document is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe severe obesity or the procedure in detail – a member of your healthcare team should give you full information and advice about these. The document includes some questions you may want to ask your surgeon to help you reach a decision. Some sources of further information and support are on page 8.

What has NICE said?

Although there is evidence to say that this procedure is safe in the short term, there are still uncertainties about how safe it is in the long term (particularly to do with reversing the procedure, and how it could affect the safety of future surgery on the stomach). There is some evidence to say that this procedure works in the short and medium term, but more evidence is needed about how well it works in the long term. If a surgeon wants to use keyhole surgery to treat severe obesity by stitching folds in the stomach to make it smaller, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this document and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

Only units specialising in weight loss surgery that can offer the procedure as one of a range of treatment options should carry out the procedure. This is in line with existing NICE guidance on obesity available from <http://guidance.nice.org.uk/CG43>

NICE has encouraged research on treating severe obesity using keyhole surgery to stitch folds in the stomach to make it smaller. The research should look at how safe the procedure is and how well it works in the long term, including how it could affect future surgery on the stomach.

Stitching folds in the stomach to make it smaller using keyhole surgery

This procedure is not the only possible treatment for obesity.

Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is 'laparoscopic gastric plication'.

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

Severe obesity is defined as a body mass index (BMI) of 40 kg/m² or more, or between 35 kg/m² and 40 kg/m² when the person also has related conditions such as high blood pressure or diabetes. Severe obesity is usually managed with changes to diet, exercise, lifestyle changes and sometimes medication. If these approaches don't help people to lose enough weight, weight loss surgery (known as bariatric surgery) is sometimes considered as a treatment option. Weight loss surgery aims to help people lose weight and keep it off by making the body absorb less food, or by making the stomach smaller so that the person feels fuller quicker and eats less food. Some of techniques are reversible, but others are not. After weight loss surgery, patients are advised to follow a special diet.

Laparoscopic gastric plication aims to help people lose weight by making the stomach smaller. It is carried out using keyhole surgery through several (usually 5 or 6) small cuts in the abdomen (belly). It involves folding part of the stomach inwards and stitching it together with a row of stitches. This can make the space that can hold food around two-thirds smaller. None of the stomach is removed, so the procedure is potentially reversible. After the operation, patients are first given a fluid diet, then slowly change to semi-solid foods, and avoid solid foods for about 6 weeks.

What does this mean for me?

If your surgeon has offered to make your stomach smaller by stitching folds in it using keyhole surgery, he or she should tell you that NICE has decided that although it is known that in the short term the procedure is safe and that there is some evidence that it works, there are uncertainties about how safe it is and how well it works in the long term. This does not mean that the procedure should not be done, but that your surgeon 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 document, and have the opportunity to discuss it with your surgeon 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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

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

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 5 studies on this procedure.

How well does the procedure work?

Three studies looked at how much excess weight patients lost after having the procedure.

In 1 of these studies, which included 100 patients, 72 patients had lost an average of 54% of their excess weight after 6 months, and 50 patients had lost an average of 60% after 24 months. In another study of 135 patients, after an average of 23 months patients had lost an average of 65% of their excess weight.

In the study of 135 patients, 29 patients lost less than 50% of their excess weight, and 8 lost less than 30% of their excess weight, after an average of 23 months.

A study of 42 patients who lost an average of 20% of their excess weight after 1 month showed that none of them put the weight back on after 18 months.

The study of 100 patients looked at 38 patients who had other health issues when they had this procedure. After 6 months, 15 out of 21 patients had improved back pain, 8 out of 13 patients had improvements in their diabetes, 6 out of 9 patients had improvements in their high blood pressure, and there were improvements for all 3 patients with sleep apnoea (interrupted breathing during sleep).

As well as looking at these studies, NICE also asked expert advisers for their views. They said that loss of excess weight after 3, 5 and 10 years, and how well the stitches are holding the stomach in place after a year, are also important in determining how well the procedure has worked.

Risks and possible problems

In the study of 135 patients, 1 patient needed to have a small part of their small intestine removed by open surgery 24 days after the procedure because of a blood clot, 2 patients needed to have a stomach blockage treated by re-doing the stitches using keyhole surgery 3 months after the procedure, 1 patient needed to have a stomach blockage caused by a protrusion between the stitches treated by re-doing the stitches after 14 months, and 2 patients had bleeding in the gut between 5 and 30 days after the procedure, which stopped on its own.

In the study of 100 patients, 1 patient had a hole in their gut repaired by open surgery 3 days after the procedure. One patient had an infected blood-filled swelling on their liver after 6 months, which was drained using keyhole surgery. For 2 weeks after the procedure, 2 patients had jaundice (a yellowing of the skin and eyes caused by a build-up of a waste product from the liver) which went away without treatment, and 1 patient had low blood levels of calcium.

Out of 355 patients in 3 studies, 4 had leakage from the gut caused by the procedure. In 1 of these patients, a leak caused peritonitis (inflammation of the thin layer of tissue that lines the inside of the abdomen) 3 days after the procedure. This was treated by cleaning the stomach and stitching the leak hole using keyhole surgery, and antibiotics. In 1 patient a leak caused by forceful vomiting 2 days after the procedure was treated by re-doing the stitches.

In the study of 135 patients, in 93 patients who had a single fold stitched into their stomachs, most had nausea and vomiting for 2–20 days, but the 42 patients who had more than 1 fold stitched into their stomachs had nausea and vomiting for only a few hours. In the study of 100 patients, 1 patient had vomiting and discomfort caused by

the stomach becoming attached to the liver, until this was operated on after 8 months.

As well as looking at these studies, NICE also asked expert advisers for their views. They said a possible problem was stitches breaking, causing weight to be regained. In theory, other problems could include bleeding during the procedure, injury to the spleen, problems with the blood supply to the stomach, and difficulty swallowing.

More information about obesity

NHS Choices (www.nhs.uk) may be a good place to find out more.

For details of all NICE guidance on obesity, visit our website at www.nice.org.uk

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. HealthTech guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. 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

This document is about 'Laparoscopic gastric plication for the treatment of severe obesity'. This document and the full guidance aimed at healthcare professionals are available at <http://guidance.nice.org.uk/HTG293>

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on [Accessibility](#) at the bottom of the NICE homepage to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this document in their own information about this procedure.

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ISBN 978-1-4731-8616-3

Nov 12

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