

Gastroelectrical stimulation for gastroparesis

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

December 2004



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Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0781.

A version in Welsh and English is also available, reference number N0782. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0782. The NICE interventional procedures guidance on which this information is based is available from the NICE website (www.nice.org.uk/IPG103guidance). Copies can also be obtained from the NHS Response Line, reference number N0780.

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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 gastroelectrical stimulation. 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 gastroelectrical stimulation is safe enough and works well enough for it to be used routinely for the treatment of gastroparesis (this is where the stomach takes too long to empty its contents into the next part of the digestive system).

To produce this guidance, NICE has:

- looked at the results of studies on the safety of gastroelectrical stimulation 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 gastroelectrical stimulation for gastroparesis

Gastroparesis happens when the nerve supply to the stomach becomes damaged or stops working. The result is that the stomach doesn't work normally, and it takes longer than usual for the partially digested food to move into the intestine. The person may feel sick or have long periods of vomiting. They may also have abdominal bloating or pain. In severe cases, the person can become malnourished.

Gastroparesis can affect people with type 1 diabetes, though it can also accompany anorexia nervosa and a condition known as abdominal migraine, where the person (usually a child) has repeated attacks of intense abdominal pain that last 1–72 hours. In between attacks, there are no symptoms.

For gastroelectrical stimulation, the stomach is connected to a stimulating device that's positioned in a small 'pocket' made in the skin of the abdomen. When the stimulating device is turned on, it sends electrical impulses to the stomach that help it to work normally. The amount of stimulation can be adjusted to suit the patient.

How well it works

What the studies said

There have not been many good-quality studies on gastroelectrical stimulation. In one study that followed what happened in patients for 12 months after the stimulating device had been put in, people went from being sick around 17 times a week to being sick about 5 times a week (on average). Other symptoms also generally improved.

In another study, nausea and vomiting were also generally reduced a year after having the device inserted. But stomach emptying had slowed down again in some patients by this time.

In a third study, all the patients were fitted with the stimulating device, but half of them had it switched off for a month while the other half had it switched on. After a month, the groups were switched so that the other half had the device switched on. The patients didn't know whether their device was on or off, but they used it as if it was switched on. The study showed when the stimulating device was switched on, patients had fewer periods of vomiting.

What the experts said

The experts said that it still isn't clear how well gastroelectrical stimulation works. In particular, it's not clear whether the stimulating device is directly helping symptoms such as vomiting, or whether it's helping these by making the stomach speed up.

Risks and possible problems

What the studies said

Data collected on problems affecting patients after they'd had the stimulating device put in gave the following information:

- around one in four patients had pain around the abdomen
- about one in five patients had problems linked to the stimulating device or the connecting leads (in some cases, this meant that the stimulating device had to be removed).

The problems linked to the stimulating device included:

- infection, which affected 1 person in 25

- movement of the device, which affected 1 person in 50
- damage to the stomach wall, which affected 1 person in 50.

What the experts said

The experts did not have any particular concerns about the safety of gastroelectrical stimulation. They listed the possible problems as infection around the stimulating device, wearing of the leads connected to the stomach, and blockage of the small intestine.

What has NICE decided?

NICE has decided that, if a doctor wants to carry out gastroelectrical stimulation for gastroparesis, he or she should make sure that the patient understands what is involved and that there are still uncertainties over the safety of the procedure and how well it works. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place.

NICE has also recommended that the device should only be fitted in specialist gastroenterology units where the doctors and health staff have expertise in conditions such as gastroparesis.

NICE has also pointed out that at the moment it isn't clear that using the stimulating device has an effect on stomach emptying. More studies are needed on this, and NICE may look at this procedure again if more information is published.

What the decision means for you

Your doctor may have offered you gastroelectrical stimulation for gastroparesis. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the benefits and risks of gastroelectrical stimulation for gastroparesis which you need to understand before you agree to it. Your doctor should discuss these with you. Some of them 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 gastroelectrical stimulation for gastroparesis is on the NICE website (www.nice.org.uk/IPG103guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0780. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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

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