



# Implantation of a duodenal-jejunal bypass liner for managing type 2 diabetes

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## What has NICE said?

There is not enough evidence to be sure about how well an implanted <u>duodenal-jejunal</u> <u>bypass liner</u> works or how safe it is for managing <u>type 2 diabetes</u>. For this reason, it should only be done as part of a research study. NICE may look at it again if more evidence is published.

#### What does this mean for me?

Your health professional can only offer you this procedure as part of a research study. Details of your procedure will be collected.

#### Other comments from NICE

NICE said that the procedure is promising but more evidence is needed. It also noted that

the safety of the procedure and how well it works may be influenced by ongoing new developments.

### The condition

In type 2 diabetes, the levels of sugar in the blood are too high because the body cannot make enough of a hormone (called insulin) or the body cannot use the insulin it produces properly (called insulin resistance). Insulin controls the level of sugar (glucose) in the blood. Type 2 diabetes is most common in people with obesity or who are overweight. Type 2 diabetes is often associated with raised blood pressure and high cholesterol levels.

Type 2 diabetes is managed by lifestyle and dietary changes, exercise and antidiabetic medicines. If these things don't control blood sugar levels properly, insulin injections may be needed.

NICE has looked at using a duodenal-jejunal bypass liner as an add-on treatment option.

NHS Choices (<u>www.nhs.uk</u>) and <u>NICE's information for the public about type 2 diabetes</u> may be a good place to find out more.

# The procedure

This procedure aims to lower blood sugar levels by acting as a barrier between food and the upper part of the bowel. It delays food mixing with digestive juices.

Under a general anaesthetic or sedative, a thin flexible tube with a camera on the end (endoscope) is inserted into the patient's mouth and moved through the food pipe and stomach into the bowel. The liner is moved through the tube, attached to the upper part of the bowel by a metal anchor and then extended about 60 cm down the bowel.

Straight after the procedure, patients can only have fluids, and then move on to eating semi-solid foods and solid foods over several weeks. The liner is removed within a year under a sedative and using an endoscope.

## Benefits and risks

When NICE looked at the evidence, it decided that there is not enough evidence to be sure about how well an implanted duodenal–jejunal bypass liner works or how safe it is for managing type 2 diabetes. The 8 studies that NICE looked at involved a total of 186 patients.

Generally, they showed the following minimal benefits:

- a 1% fall in HbA<sub>1c</sub> levels at 6 months
- slightly improved blood sugar levels at 6 months after the liner was removed
- slight fall in blood pressure at 1 year
- reduced total cholesterol and triglycerides at 1 year
- improvement in insulin resistance at 6 months
- a decrease in the amount of insulin and antidiabetic medicine used at 1 year
- successful insertion of the liner in 96% of patients (in 4%, the liner was difficult to insert)
- no differences in most outcomes at 1 year between the procedure plus diet and diet alone.

The studies showed that the risks of an implanted duodenal–jejunal bypass liner included:

- early removal of the liner because of problems (pain, bleeding in the gut and movement of the liner) in 25–40% of patients
- pancreatitis in 2 patients
- pain and other minor symptoms in the digestive tract in 63% of patients
- nausea and vomiting in 24% of patients
- liner-related back pain in 23% of patients
- mild-to-moderate low blood sugar in 24% of patients (but this was similar in patients without the liner)

- metabolic and nutritional disorders in 61% of patients
- a hole in the bowel in 1 patient; the liner was removed and the damage repaired surgically
- a hole in the food pipe while the liner was being removed in 1 patient, which needed treatment and healed after 3 weeks.

NICE was also told about some other possible risks: difficulties in inserting the liner; having to stop the procedure because of food left in the stomach; cramping; intussusception (an emergency when 1 part of the gut slides into the next part); misplacement of the liner hood or blockage at the top of the throat while the liner is being removed.

If you want to know more about the studies, see the <u>guidance</u>. Ask your health professional to explain anything you don't understand.

# Questions to ask your health professional

- 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?

# About this information

NICE <u>interventional procedures guidance</u> advises the NHS on the safety of a procedure and how well it works.

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# Accreditation

