NICE guidance

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

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

1.1 Current evidence on the safety and efficacy of implantation of a duodenal–jejunal bypass liner for managing type 2 diabetes is limited in quality and quantity. Therefore, the procedure should only be used in the context of research.

1.2 Further research should give details of patient selection, including information about use of the procedure in patients with different levels of body mass index (BMI). The research should provide information on complications; reasons for early removal of the device; medication used for treating type 2 diabetes, both when the device is in place and after its removal; and control of type 2 diabetes after device removal. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 Type 2 diabetes is caused by insulin resistance with or without inadequate pancreatic insulin secretion. It is most commonly seen in people with obesity or who are overweight. Presenting symptoms include polyuria, polydipsia and fatigue. Type 2 diabetes is commonly associated with raised blood pressure, abnormal blood lipid levels and a tendency to atherosclerosis. This combination is often described as the 'metabolic syndrome', which is associated with fatty liver and abdominal adiposity (increased waist circumference).

2.2 Type 2 diabetes is managed by lifestyle and dietary changes, exercise and oral antidiabetic drugs (as recommended in NICE's guideline on type 2 diabetes). If

blood glucose levels remain poorly controlled, subcutaneous insulin injections may be needed.

3 The procedure

3.1 Endoscopic implantation of a duodenal–jejunal bypass liner (DJBL) is a procedure that aims to improve glycaemic control in people with obesity or who are overweight.

3.2 The procedure is done with the patient under general anaesthesia or sedation, using image guidance. The liner is positioned endoscopically (via the mouth). Using a delivery catheter, a capsule containing a single-use impermeable DJBL is positioned in the duodenal bulb just distal to the pylorus. It is secured there using an integral spring metal anchor. The liner is advanced distally into the jejunum using a tension wire that is part of the 'introducer' device. It extends about 60 cm down the small intestine and forms a barrier between food and the intestinal wall, delaying the mixing of digestive enzymes with food.

3.3 After the procedure, patients are recommended a diet that typically involves progression from fluids to semi-solid foods and then to solid foods.

3.4 After a maximum of a year, the liner is removed with the patient under sedation, using image guidance and endoscopy. The anchor has a drawstring mechanism such that it can be collapsed and partly withdrawn into a plastic hood fitted to the endoscope before withdrawal.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

4.1 A randomised controlled trial (RCT) of 77 patients with obesity and type 2 diabetes compared duodenal–jejunal bypass liner (DJBL) treatment in

combination with dietary intervention (n=38) against dietary intervention alone (n=39) for 6 months. It reported that glycated haemoglobin (HbA1c) levels improved from 8% at baseline to 7% in the DJBL plus diet group, but remained at about 8% in the diet-alone group at 6-month follow-up. The difference between the 2 groups was significant ($p<0.05$).

4.2 The RCT of 77 patients reported that, at 12-month follow-up (including 6 months after DJBL removal), fasting glucose levels had decreased from 11.0 to 9.0 mmol per litre in the DJBL plus diet group compared with 9.7 mmol per litre in the diet-alone group. The difference between the 2 groups was not significant ($p=0.41$).

4.3 The RCT of 77 patients reported that, at 12-month follow-up (including 6 months after DJBL removal), fasting insulin levels remained the same in the DJBL plus diet group (15.0 mU per litre), and decreased in the diet-alone group (from 17.0 to 15.7 mU per litre). The difference between the 2 groups was not significant ($p=0.73$).

4.4 A case series of 22 patients with obesity and type 2 diabetes treated with a DJBL reported that improved glycaemic control (mean percentage decrease of -1.7±0.7% in HbA1c from a baseline level of 8.9±1.7%) continued for up to 6 months after device removal in 11 patients.

4.5 The RCT of 77 patients reported that, at 12-month follow-up, blood pressure had decreased from 147/92 to 130/82 mmHg in the DJBL plus diet group and from 152/90 to 140/85 mmHg in the diet-alone group. The difference between the 2 groups was not significant ($p=0.31$ for systolic pressure and $p=0.38$ for diastolic pressure). At 12-month follow-up, total cholesterol levels were comparable with those at baseline and the difference between the 2 groups was not significant (4.4 mmol per litre in both groups; $p=0.79$).

4.6 The case series of 22 patients reported significant reductions in total cholesterol (mean decrease of -19.7±5.9 mg per dl from a baseline level of 201±37 mg per dl; $p<0.01$) and triglycerides (mean decrease of -44.8±17.4 mg per dl from a baseline level of 213±89 mg per dl; $p<0.05$) at last observation on or before device removal.

4.7 A case series of 81 patients reported improvement in insulin resistance, with a significant reduction in triglyceride/high-density lipoprotein (HDL) ratio from 5.75 to 4.36 ($p<0.001$). Also, 43% of patients had a triglyceride/HDL ratio lower than 3.5, 6 months after DJBL implantation.

4.8 In the RCT of 77 patients, at 12-month follow-up, the daily insulin dose and use of sulfonylureas had decreased or the medication had been stopped in the DJBL plus diet group more often than in the diet-alone group ($p<0.05$).

4.9 In the case series of 81 patients, the DJBL could not be implanted in 4% (3 out of 81) of patients because they had a short duodenal bulb.

4.10 The specialist advisers listed key efficacy outcomes as reduced insulin resistance leading to improved glycaemic control; reduction in HbA1c, hypoglycaemic medication use, fasting insulin, C-peptide and Homeostatic Model Assessment of Insulin Resistance (HOMA-IR); and improvement in hypertension and quality of life, both in the short and long term (that is, after the device has been removed).

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

5.1 Perforation of the duodenal bulb was seen 4 weeks after implantation of a duodenal–jejunal bypass liner (DJBL) in a case report of 1 patient. The device was removed endoscopically and the perforation was closed laparoscopically with a running suture. The patient was discharged 9 days after the surgery.

5.2 Oesophageal perforation during device removal at 6 months (caused by one of the barbs on the anchor not being covered by the removal hood) was reported in 1 patient in the DJBL plus diet group (n=38) in a randomised controlled trial (RCT) of 77 patients with obesity and type 2 diabetes. This was treated by endoscopic stenting and placement of a feeding tube. The tear had resolved without sequelae by 3 weeks.

5.3 Early removal of the device was needed in 40% (9 out of 22) of patients in a case series of 22 patients. This was because of: device migration or rotation in 3 patients (within 48 weeks after implantation); gastrointestinal bleeding in 1 patient (at 4 weeks); abdominal pain in 2 patients (at 24 and 30 weeks); principal investigator request because of non-compliance with follow-up in 2 patients (at 20 and 32 weeks); and discovery of an unrelated malignancy in 1 patient (at 17 weeks).

5.4 In a case series of 79 patients (21 with type 2 diabetes), 26% (21 out of 79) of devices were removed early because of: device migration (n=8); device obstruction (n=5); abdominal pain (n=2); liver abscess (n=1); upper gastrointestinal bleeding (n=1); cholangitis (n=1); ulcerative colitis (n=1); acute cholecystitis (n=1); or patient request (n=1).

5.5 Pancreatitis was reported in 2 patients in a case series of 152 patients. Further management details were not reported (conference abstract).

5.6 Upper abdominal pain, minor gastrointestinal symptoms or discomfort were reported in 63% (25 out of 38) of patients in the DJBL plus diet group and 28% (11 out of 39) of patients in the diet-alone group in the RCT of 77 patients. Nausea and vomiting occurred in 24% (9 out of 38) of patients in the DJBL plus diet group and in 18% (7 out of 39) in the diet alone group, all of whom were managed conservatively.

5.7 Device-related back pain was reported in 23% (5 out of 22) of patients in the case series of 22 patients.

5.8 Mild-to-moderate hypoglycaemia was reported in 24% (9 out of 38) of patients in the DJBL plus diet group and 26% (10 out of 39) of patients in the diet-alone group in the RCT of 77 patients.

5.9 Metabolic and nutritional disorders, including hypoglycaemia and iron deficiency, occurred in 61% (14 out of 23) of patients in a case series of 23 patients. Further details were not reported.

5.10 The specialist advisers listed anecdotal adverse events as difficulties in deploying the device; halting the procedure after endoscopy because of residual food in the

stomach; cramping; intussusception; pharyngeal obstruction during device removal; and misplacement of the device hood in the pharynx during device removal. The specialist advisers listed theoretical adverse events as peritonitis; aspiration; infection; dehydration; constipation; belching; bloating; diarrhoea; gastro-oesophageal reflux disease; oesophagitis; duodenitis; pseudopolyps; peptic ulcer disease; and adynamic ileus.

6 Committee comments

6.1 The Committee considered that implantation of a duodenal–jejunal bypass liner for managing type 2 diabetes is a promising procedure that might provide benefit for many patients if further evidence supports its efficacy and safety.

6.2 In recommending further research, the Committee recognised that well-organised prospective data collection has the potential to contribute to the evidence base, in addition to randomised controlled trials.

6.3 The Committee noted that technological developments are occurring in the design and implantation of duodenal–jejunal bypass liners, which may influence their efficacy and safety.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.