NICE guidance

Laparoscopic gastrectomy for cancer

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 Guidance

1.1 Current evidence on the safety and efficacy of laparoscopic gastrectomy for cancer appears adequate to support the use of this procedure, provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 This procedure is technically demanding. Surgeons undertaking it should have specific training and special expertise in laparoscopic surgical techniques, and should perform their initial procedures with an experienced mentor.

1.3 Patient selection and management should be carried out in the context of a multidisciplinary team with established experience in the treatment of gastric cancer.

2 The procedure

2.1 Indications and current treatments

2.1.1 Over 95% of gastric cancers originate from the cells of the stomach lining (adenocarcinoma). This guidance applies only to adenocarcinoma. Symptoms may include heartburn, dysphagia and weight loss. Nausea and vomiting may also occur and gastric bleeding may lead to anaemia.

2.1.2 For patients whose gastric cancer is diagnosed at a stage that is amenable to surgical treatment, the options include open or laparoscopic gastrectomy.

2.2 Outline of the procedure

2.2.1 Under general anaesthesia, a laparoscope and trocars are inserted through small incisions in the abdominal wall. A larger incision may also be made so that a hand can be introduced into the peritoneal cavity for hand-assisted laparoscopic gastrectomy or laparoscopically assisted digital gastrectomy (LADG). Surgery may take the form of total or partial gastrectomy (either proximal or distal), depending on the site of the tumour. Removal of draining lymph nodes is an integral part of the procedure.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, see the overview.

2.3.1 A multicentre case series of 1,294 patients with early gastric cancer treated with laparoscopic gastrectomy reported 5-year disease-free survival of 99.8% for stage IA disease, 98.7% for stage IB disease, and 85.7% for stage II disease. In a second case series of 100 patients with advanced disease, 5-year overall and disease-free survival rates were 59% and 57%, respectively.

2.3.2 In a non-randomised controlled trial of 102 patients, the mortality rate due to cancer recurrence among the 44 patients treated with LADG was 5% (2 out of 44) at mean follow-up of 14 months. In a second non-randomised controlled trial of 52 patients, 4% (1 out of 24) of the 24 patients treated with either partial or total laparoscopic gastrectomy had died of metastatic cancer at 1-year follow-up.

2.3.3 In the non-randomised controlled trial of 102 patients, including 44 patients treated with laparoscopic gastrectomy, and two case series of 1,294 and 100 patients treated with laparoscopic gastrectomy, conversion from laparoscopic to open surgery was reported in 2% (1 out of 44), 1% (14 out of 1,294) and 3% (3 out of 100), respectively. Reasons for conversion included anatomical constraints, bleeding and mechanical problems.

2.3.4 In a meta-analysis of 1,611 patients with early gastric cancer, including 837

treated with laparoscopic procedures, significantly fewer lymph nodes were removed by LADG than by open distal gastrectomy (weighted mean difference -4.35 nodes, 95% confidence interval -5.73 to -2.98 nodes, p<0.001).

2.3.5 The Specialist Advisers considered key efficacy outcomes to include 30-day mortality, cancer-free survival rates, adequate surgical margins, and number of lymph nodes removed.

2.4 Safety

2.4.1 The meta-analysis of 1,611 patients (837 patients treated with laparoscopic procedures) reported that there were fewer complications overall following LADG (11% [58 out of 535]) than following open gastrectomy (18% [97 out of 519]; odds ratio [OR] 0.54; p<0.001). However, there was no significant difference between the groups with respect to rates of mortality, anastomotic leak, stricture or wound infection.

2.4.2 The multicentre case series reported perforation (not otherwise described) in <1% (1 out of 1,294) of patients. The non-randomised controlled trial of 102 patients (44 undergoing laparoscopic procedures) reported that there were more cases of pulmonary infection following open gastrectomy (10% [6 out of 58]) than following LADG (2% [1 out of 44]) for gastric cancer (non-significant: p=0.110).

2.4.3 The reported rate of postoperative bleeding ranged from 0.2% (1 out of 586) to 2% (1 out of 44) across the included studies.

2.4.4 In the meta-analysis there were significantly fewer cases of ileus following LADG than following open gastrectomy (OR 0.27; p<0.02). In the multicentre case series, ileus following laparoscopic gastric resection occurred in <1% (3 out of 1,294) of patients.

2.4.5 The Specialist Advisers stated that anecdotal adverse events include port insertion injury to intra-abdominal organs or vessels, bleeding, venous thromboembolism, complications of prolonged pneumoperitoneum, anastomotic or duodenal stump leak, chyle leaks, incomplete resection and anastomotic stricture. They also listed theoretical adverse events, including inadequate

lymphadenectomy, cancer seeding, Roux limb ischaemia, cardiac complications and port-site hernias.

2.5 Other comments

2.5.1 The Committee noted that most of the evidence on this procedure relates to practice in parts of Asia, where gastric cancer is substantially more common than in the UK, population screening leads to detection of many cancers at an early stage and laparoscopic gastrectomy is frequently used for early-stage gastric cancer.

2.5.2 The Committee noted concerns about the possibility that removing fewer lymph nodes in a laparoscopic procedure compared with an open procedure might result in increased tumour recurrence. However, the evidence on survival showed no difference. Further publication of long-term outcomes would be useful.

2.5.3 Clinicians wishing to undertake this procedure are encouraged to submit data to the Minimally Invasive Gastro-Oesophageal Cancer Surgery (MIGOCS) database supported by the Association of Upper Gastrointestinal Surgeons and the Association for Laparoscopic Surgeons.

3 Further information

3.1 NICE has produced a guideline on colorectal cancer and technology appraisal guidance on imatinib for the treatment of unresectable and/or metastatic gastrointestinal stromal tumours.

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 decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.