

Minimally invasive oesophagectomy

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg407

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.

This guidance replaces IPG189.

1 Guidance

- 1.1 Current evidence on the efficacy and safety of minimally invasive oesophagectomy (MIO) is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit with local review of results.
- 1.2 Patient selection should be done by a multidisciplinary team specialising in the management of oesophageal cancer.
- 1.3 MIO is a technically challenging procedure, which should only be carried out by surgeons with special expertise and specific training. They should perform their initial operations with an experienced mentor.
- 1.4 Clinicians should enter details about all patients undergoing MIO onto the National Oesophago-Gastric Cancer Audit.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Oesophagectomy is used to treat resectable cancer of the oesophagus. It is also a treatment option for Barrett's oesophagus with high-grade dysplasia. Conventionally, oesophagectomy is performed using open surgery.

2.1.2 Depending on the tumour type, location and stage, oesophagectomy may involve a total or partial resection of the oesophagus, with or without dissection of regional lymph nodes. Total oesophagectomy involves both a thoracic incision to mobilise the oesophagus and an abdominal incision to dissect and prepare the stomach (or sometimes intestine) for anastomosis to the remaining upper oesophagus or pharynx. The new gastric tube is then drawn up the chest to the level of the healthy oesophageal remnant, and an anastomosis is performed, usually via a cervical incision. In some patients (typically with lower-third tumours), partial oesophagectomy may be carried out transhiatally using only an abdominal incision. There are a number of technical variations in the way the open oesophagectomy can be done.

2.2 Outline of the procedure

- 2.2.1 Minimally invasive oesophagectomy (MIO) aims to achieve the same result as open oesophagectomy but with less postoperative morbidity.
- 2.2.2 The procedure is performed with the patient under general anaesthesia. Single-lung ventilation is required for the thoracic part of the operation (except for transhiatal techniques). MIO involves performing oesophagectomy under thoracoscopic and laparoscopic visualisation. However, hybrid MIO (HMIO) techniques, which combine either thoracoscopy or laparoscopy with open surgery (for the abdominal or the thoracic component of the procedure respectively), are also described as minimally invasive.
- 2.2.3 Thoracic and/or abdominal carbon dioxide (CO₂) insufflation is used, and a number of incisions are made to accommodate camera and instrument ports. Following resection of the oesophagus, anastomosis is performed either via an (open) cervical approach or an intrathoracic endoscopic approach using stapling devices.
- 2.2.4 MIO is a complex procedure and the operating time may be long.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and 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](#).

- 2.3.1 A study of routine hospital episodes statistics data compared 699 patients treated by MIO or HMIO versus 17,974 patients treated by open oesophagectomy. Based on data available for 41% (7,724 out of 18,673) of patients, and after adjusting for age, gender, socioeconomic deprivation, comorbidity score, year of operation and number of emergency hospital admissions in the previous year, there was some evidence that patients undergoing MIO or HMIO had lower 1-year mortality than patients treated by open oesophagectomy (odds ratio [OR] 0.68, 95% confidence interval [CI] 0.46 to 1.01, $p=0.058$).
- 2.3.2 Two non-randomised studies comparing HMIO versus open oesophagectomy reported cancer recurrence rates of 6% (1 out of 17) and 0% (0 out of 14) respectively (undefined follow-up interval); and 19% (3 out of 16) and 7% (2 out of 28) at 44-month follow-up (significance not stated). Three non-randomised comparative studies, including in total 143 patients, 73 treated by HMIO and 70 treated by open surgery, reported recurrence rates ranging from 0% to 44% in patients treated by HMIO and from 3% to 50% in those treated by open surgery (follow-up ranging from 6 months to 54 months). Another non-randomised comparative study comparing 165 patients treated by HMIO versus 56 treated by open surgery reported no significant association for either technique with cancer recurrence (rate of recurrence: 58% for HMIO and 68% for open surgery; follow-up not stated).
- 2.3.3 A non-randomised comparative study comparing 27 patients treated by HMIO against 29 patients treated by open surgery assessed quality of life in 5 domains of the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 and QLQ-OES18 questionnaires (fatigue, pain, dyspnoea, physical functioning, global quality of life). Both patient groups had similar preoperative scores. Compared with baseline, quality-of-life scores deteriorated in all 5 domains at 2 weeks in both groups, although the scores were worse in the open surgery group. Over time, quality-of-life scores improved in both groups. At 24-week follow-up there were statistically significant differences between the 2

groups for physical functioning (mean score of 84 for HMIO versus 76 for open surgery) and global quality of life (mean score of 75 for HMIO versus 68 in the open surgery group).

- 2.3.4 The Specialist Advisers considered key efficacy outcomes to include speed of postoperative recovery compared with open surgery, cancer recurrence, overall survival, quality of life, and more frequent need for cervical anastomosis compared with open surgery.

2.4 Safety

- 2.4.1 Thirty-day in-hospital mortality was reported as 2% (1 out of 50) in patients treated by MIO and 3% (1 out of 30) in patients treated by open surgery in a non-randomised comparative study of 80 patients. Two non-randomised comparative studies comparing 15 and 18 patients treated by MIO with 30 and 36 patients treated by open surgery, respectively, reported no in-hospital deaths within 30 days of the procedure. A non-randomised comparative study of 90 patients reported 30-day in-hospital mortality of 7% (3 out of 44) after MIO and 4% (2 out of 46) after open oesophagectomy.
- 2.4.2 Two non-randomised comparative studies reported 30-day in-hospital mortality of 2% (1 out of 45) and 5% (1 out of 22) in patients treated by HMIO, while no deaths were reported in the 26 and 63 patients treated by open oesophagectomy. Six non-randomised comparative studies comparing a total of 475 patients treated by MIO with 434 treated by open surgery reported that 30-day in-hospital mortality was higher after open surgery (10% versus 14%, 6% versus 11%, 0% versus 5%, 0% versus 7%, 3% versus 6%, and 3% versus 8%; level of significance not stated).
- 2.4.3 Two non-randomised comparative studies reported 30-day in-hospital mortality of 5% (1 out of 22) and 4% (2 out of 56) in patients treated by MIO or HMIO, and 9% (4 out of 43) or 6% (6 out of 98) in those treated by open oesophagectomy (follow-up and significance not stated).
- 2.4.4 In the study of routine hospital episodes statistics data comparing 699 patients treated by MIO or HMIO versus 17,974 patients treated by open oesophagectomy,

and based on data available for 49% (9,217 out of 18,673) of patients, after adjusting for age, gender, socioeconomic deprivation, comorbidity score, year of operation, and number of emergency hospital admissions in the previous year, there was no significant difference between the comparator groups for 30-day in-hospital mortality (OR=0.99, 95% CI 0.68 to 1.44, p=0.936).

- 2.4.5 A non-randomised comparative study of 41 patients treated by MIO, 34 by HMIO and 46 by open surgery reported 30-day in-hospital mortalities of 2%, 6% and 2% respectively. A non-randomised comparative study of 23 patients treated by MIO, 309 by HMIO and 114 by open surgery reported 30-day in-hospital mortalities of 0%, 2% and 3% respectively.
- 2.4.6 Anastomotic leakage rates ranged from 0% to 20% among patients treated by either MIO or HMIO, and from 2% to 29% among patients treated by open surgery in 21 non-randomised comparative studies (total number of patients: 1,371 MIO or HMIO, 1,114 open). Among patients with anastomotic leakage, rates of reoperation ranged from 0% to 19% in patients treated by MIO or HMIO and from 0% to 26% in patients treated by open surgery in all but 1 study, which reported a 76% reoperation rate for open surgery patients. Case series of 222 and 282 patients reported that 12% (26 out of 222) and 13% (36 out of 282) of patients developed an anastomotic leak.
- 2.4.7 Tracheal perforation occurred in 5% (1 out of 22) and 0% (0 out of 21) of patients treated by HMIO and in 13% (8 out of 63) and 5% (1 out of 21) of patients treated by open surgery in 2 non-randomised comparative studies. Intraoperative tracheal perforation (described as minor) occurred in less than 1% (2 out of 222) of patients in a case series. Tracheal tear occurred in 2 patients in each of 2 case series (222 and 282 patients).
- 2.4.8 Damage to adjacent organs (not otherwise specified) occurred in 0% to 8% of patients treated by MIO or HMIO and in 0% to 15% of patients treated by open surgery in 5 non-randomised comparative studies (total number of patients: 157 MIO or HMIO, 176 open). One case report described injury to the supradiaphragmatic aorta during the laparoscopic phase of an oesophagectomy requiring conversion to open surgery. Another case report described injury to an aberrant right subclavian artery during thoracoscopic mobilisation of the oesophagus which was successfully repaired.

- 2.4.9 Tension capnothorax was described in 1 case report, requiring conversion to open surgery.
- 2.4.10 Chyle leakage rates ranged from 0% to 9% in patients treated by MIO or HMIO and 0% to 7% in patients treated by open surgery in 11 non-randomised comparative studies (total number of patients: 752 MIO or HMIO, 525 open). Two case series reported chylothorax in 3% (7 out of 222) and 2% (7 out of 282) of patients.
- 2.4.11 Laryngeal nerve or vocal cord damage rates ranged from 0% to 33% in patients treated by MIO or HMIO and 0% to 42% in patients treated by open surgery in 17 non-randomised comparative studies (total number of patients: 965 MIO or HMIO, 757 open). The case series of 222 patients reported vocal cord palsy in 4% (8 out of 222) of patients. The case series of 282 patients reported recurrent laryngeal nerve injury in 5% (15 out of 282) of patients.
- 2.4.12 The Specialist Advisers listed anecdotal adverse events as major intrathoracic bleeding, damage to vital structures, injury to the trachea and bronchi during thoroscopic dissection, and gastric necrosis.

2.5 Other comments

- 2.5.1 The Committee noted the possibility of bias and confounding within the published studies. However, the studies included large numbers of patients and showed no consistent differences in any efficacy or safety outcomes compared with open surgery.

3 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](#).