



Endoscopic mastectomy and endoscopic wide local excision for breast cancer

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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 <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of endoscopic mastectomy and endoscopic wide local excision for breast cancer is inadequate in quantity. Therefore, these procedures should only be used in the context of research. The research should include adequacy of resection margins, survival, recurrence or reoperation rates, tumour size and location, patient breast size, quality of life, and cosmesis.
- Research should be conducted only in units specialising in the management of breast cancer, by surgeons trained in both breast cancer surgery and endoscopy.
- 1.3 NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Breast cancer is the most common cancer in women in the UK. It can be categorised into four stages, from stage 1 (an isolated tumour less than 2 cm in diameter) to stage 4 (advanced cancer), and three grades, from grade 1 (slow-growing cancer) to grade 3 (fast-growing cancer). It may be classified further, depending on protein markers present.
- 2.1.2 Treatment depends on the breast cancer type, stage and grade. Surgery is often

the first option for early breast cancer and may involve removing the whole breast (mastectomy) or part of the breast ('conservative' or 'breast conserving' surgery). Adjuvant radiotherapy, chemotherapy or endocrine therapy may be offered to reduce the risk of local tumour recurrence.

2.2 Outline of the procedure

- 2.2.1 Endoscopic mastectomy and endoscopic wide local excision for breast cancer are performed with the patient under general anaesthesia. These procedures can be performed through an axillary incision (usually), a periareolar incision, or using both types of incision. Under endoscopic guidance, carbon dioxide insufflation is used to create a working space and the breast tissue is dissected. Haemostasis is achieved by ligation and electrical coagulation. For endoscopic mastectomy, the breast tissue, including the tumour, is separated from the muscle and subcutaneous tissues, and removed. For endoscopic wide excision, the breast part containing the tumour is removed, with adequate healthy breast tissue margins. Drains are inserted and the incisions closed. Immediate reconstructive surgery may be performed if appropriate.
- 2.2.2 As with other types of breast cancer surgery, adjuvant radiotherapy, chemotherapy or endocrine therapy may also be offered.

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 detailed information on the evidence, see the <u>overview</u>.

2.3.1 A non-randomised controlled trial compared outcomes in 21 patients treated by endoscopic mastectomy and 25 patients treated by subcutaneous mastectomy without an endoscope, for early stage breast cancer (stage 1 or 2). The trial reported that all patients were alive at a median 19-month follow-up (range 5.8 to 35.2 months). A case series of 551 patients treated by endoscopic mastectomy reported distant-metastasis-free survival to be 100% in those with ductal

carcinoma in situ (a very early form of breast cancer; n=47), 96% in those with T1 tumours (less than 2 cm diameter; n=190), and 91% in those with T2 tumours (2 cm to 5 cm diameter; n=314) at 66-month follow-up.

- 2.3.2 The case series of 551 patients reported local recurrence in 4% (23 out of 551) of patients after a mean follow-up of 38.4 months.
- A case series of 20 breast cancer patients reported that, at 6-month mammography, 1 patient had microcalcification in her remaining breast, requiring total endoscopic mastectomy for multifocal carcinoma.
- In the non-randomised controlled trial of 46 patients, histological examination revealed positive resection margins requiring radiation therapy 4 weeks after surgery in 5% (1 out of 21) and 8% (2 out of 25) of patients. Two case series of 20 and 6 patients reported positive histological margins in 1 patient each, the first requiring endoscopic total mastectomy (10 days after the first operation) and the second requiring additional adjuvant radiotherapy.
- 2.3.5 The case series of 551 patients reported overall patient satisfaction results from a postal questionnaire. Of the 481 respondents, 76% (366 out of 481) reported 'good' results, 14% (66 out of 481) reported 'fair' results and 10% (49 out of 481) reported 'poor' results (not further defined) at 6-month follow-up.
- 2.3.6 The Specialist Advisers considered key efficacy outcomes to include long-term survival, adequacy of tumour clearance, tumour recurrence, cosmesis, patient satisfaction, postoperative pain control, time to return to work and length of hospital stay.

2.4 Safety

- 2.4.1 Case series of 33 and 551 patients reported nipple necrosis in 9% (3 out of 33), skin necrosis in 4% (22 out of 551) and fat and/or muscle flap necrosis in 3% (17 out of 551) of patients (time of occurrence not stated).
- 2.4.2 A case series of 82 patients with malignant tumours reported second-degree burns in 4 patients (one burn occurred during skin flap formation near the nipple

and three burns occurred during additional resection for positive surgical margins found on fast-frozen sections). In a case series of 7 patients, skin burns caused by the electrocautery were reported in 2 patients; 1 patient required skin debridement.

- 2.4.3 The case series of 82 patients reported subcutaneous haemorrhage in 7 patients and haematoma in 2 patients (reoperation not required).
- 2.4.4 The Specialist Advisers considered theoretical adverse events to include major neurovascular injury, pneumothorax, non-viable skin flaps and longer operating time than traditional open surgery.

2.5 Other comments

- 2.5.1 The Committee noted that these procedures have also been used for benign breast lesions.
- 2.5.2 The Committee noted that most of the evidence relates to East Asian patient populations with generally small breast sizes. The technique may be different in women with larger breasts.

3 Further information

3.1 NICE has published cancer service guidance, interventional procedures guidance, technology appraisals guidance and clinical guidelines on breast cancer. For more information, see our topic page on breast cancer.

Sources of evidence

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

Information for patients

NICE has produced <u>information for the public on this procedure</u>. 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 <u>Healthcare Improvement Scotland</u>.