



Transoral carbon dioxide laser surgery for primary treatment of oropharyngeal malignancy

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www.nice.org.uk/guidance/ipg484

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 impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

- 1.1 Current evidence on the efficacy and safety of transoral carbon dioxide laser surgery for the primary treatment of oropharyngeal malignancy is adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit.
- 1.2 This procedure should only be carried out by clinicians who have been trained in the use of transoral carbon dioxide laser surgery in the oropharynx.
- 1.3 Patient selection for this procedure should be done by a multidisciplinary team in accordance with the <u>NICE cancer service guidance on improving outcomes in</u> head and neck cancers.
- 1.4 Clinicians should enter details of all patients undergoing transoral carbon dioxide laser surgery for the primary treatment of oropharyngeal malignancy onto the Data for Head and Neck Oncology (DAHNO) database.

2 Indications and current treatments

2.1 Malignancies in the oropharynx (which includes the tonsils, the base of the tongue and the soft palate) are usually squamous cell carcinomas originating in the epithelial cell lining. The incidence of these malignancies has increased significantly in younger patients, probably because of the increased prevalence of human papillomavirus infection. Presenting features include a persistent sore throat, a lesion in the mouth or throat, white or red patches that may be swollen

or bleeding, and pain in the ear. Patients tend to present with advanced or sometimes metastatic disease.

Oropharyngeal malignancies can be treated by surgery (using open or minimally invasive approaches for tumour resection and reconstruction), radiotherapy, chemotherapy, or a combination of these methods. Surgical resection may include neck dissection to remove lymph nodes. When the malignancy is considered to be unresectable, palliative chemotherapy and radiotherapy can be used.

3 The procedure

- 3.1 Transoral carbon dioxide laser surgery is a minimally invasive endoscopic approach for treating tumours in the oropharynx. It is usually performed under general anaesthesia, with the patient supine and tilted head-down. The tumours are visualised using a modified mouth gag and/or an endoscope. The carbon dioxide laser device is coupled to an operating microscope and the laser beam is used to excise the tumour completely, together with an adequate margin of tissue around it. Large tumours are removed in 2 or more pieces as a multiblock resection.
- Fibre-optic carbon dioxide lasers, flexible delivery systems and robots have been developed, all of which increase the range of angles of approach that can be used to achieve tumour resection.
- Laser resection of tumours is sometimes combined with either simultaneous or staged neck dissection if there is cervical lymphadenopathy or a suspicion of occult metastases. Adjuvant radiotherapy and/or chemotherapy is also offered to some patients, based on a number of factors such as T-stage, nodal status, extracapsular spread of tumour, margin status and histology.

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

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the evidence, see the overview.

- A retrospective comparative case series of 223 patients with T1 oropharyngeal carcinoma treated by transoral carbon dioxide laser surgery (TLS) with or without neck dissection (±ND) (n=53) or by electrocautery (n=170) reported that there was no significant difference in 5-year disease-specific survival (89% for TLS±ND and 87% for electrocautery; p>0.05).
- 4.2 A prospective case series of 204 patients (of whom 203 were analysed) with stage III or IV oropharyngeal cancers treated by TLS±ND alone (53 patients) or by TLS±ND and combined adjuvant treatment (150 patients: 117 radiotherapy alone, 33 chemoradiotherapy) reported that rates of 5-year overall survival, disease-specific survival and disease-free survival were 78%, 84% and 74% respectively across all groups. TLS combined with postoperative adjuvant radiotherapy (in 117 of 204 patients) reduced the risk of death by over 50% (hazard ratio 0.33 to 0.48) compared against the risk of death in the group who received TLS±ND alone (53/204 patients).
- The retrospective comparative case series of 223 patients reported a 5-year local control rate of 95% for TLS±ND and 91% for electrocautery (p>0.05; not significant).
- The retrospective case series of 69 patients reported that 4% (3 of 69) of patients had disease recurrence at the primary site at a mean follow-up of 44 months. The 5-year local regional control rate in patients in whom adjuvant therapy was not indicated was 82%. The 5-year local regional control rate in patients who declined adjuvant therapy was 74%.
- The specialist advisers listed key efficacy outcomes as local control, survival, margin control and local recurrence.

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.

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- of patients in a retrospective case series of 48 patients with squamous cell carcinoma of the base of the tongue treated by transoral carbon dioxide laser surgery with or without neck dissection (TLS±ND) and adjuvant radiotherapy. The bleeding was from a vessel at the base of the tongue in 1 patient, at the lateral oropharyngeal wall in 1 patient, at the aryepiglottic fold in 1 patient, and from the wound cavity (no further details given) in 2 patients. All complications were managed by micropharyngoscopy with electrocoagulation. Public consultation also reported a single death due to severe haemorrhage.
- Severe dysphagia and recurrent aspiration were reported in 6% (3 of 48) of patients in the retrospective case series of 48 patients, as a result of extended tumour resection, including 'resection in adjacent sites and structures'. All 3 patients needed gastrostomy tubes.
- Airway loss (needing surgical cricothyroidotomy) was reported in 1 patient in the prospective case series of 204 patients; this occurred during reoperative resection of a tumour-positive margin.
- 5.4 Tracheostomies (permanent or temporary) were needed in 11% (6 of 53) of patients in the TLS±ND group and 5% (9 of 170) of patients in the electrocautery group in the retrospective comparative case series of 223 patients (no significance test reported).
- Bilateral hypoglossal nerve paresis (due to 'stretch-related complications' of the endoscopic approach to the pharynx) was reported in 1 patient in the prospective case series of 204 patients. Postoperative 'velopharyngeal incompetence' (not severe enough to prevent oral intake or good speech) was also reported in 11 patients. Further details were not reported.
- The specialist advisers listed theoretical adverse events as subcutaneous emphysema, numbness of the tongue, damage to the oral cavity or teeth during access retraction, and inadequate surgical margins.

6 Committee comments

- The committee noted that the published reports on transoral carbon dioxide laser surgery for the primary treatment of oropharyngeal malignancy included patients with tumours at other locations and at various stages. Almost all were case series and patients had received a variety of adjuvant therapies.
- Nevertheless, the committee considered that the available evidence was sufficient to support a conclusion that the outcomes for the transoral laser surgery procedure were similar to those for the other treatments in the reports. Its decision was influenced by the advice of specialists that transoral carbon dioxide laser surgery for primary treatment of oropharyngeal malignancy is an established treatment in UK practice.
- 6.3 The committee noted that patient feedback was unanimously positive about this procedure.

7 Further information

Information for patients

NICE has produced <u>information on this procedure for patients and carers</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>.

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Accreditation

