

# Radiofrequency cold ablation for respiratory papillomatosis

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg434](http://www.nice.org.uk/guidance/ipg434)

## 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 radiofrequency cold ablation for respiratory papillomatosis is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake radiofrequency cold ablation for respiratory papillomatosis should take the following actions:
  - Inform the clinical governance leads in their Trusts.
  - Ensure that patients and their carers or parents understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- 1.3 NICE encourages further research and data collection on radiofrequency cold ablation for respiratory papillomatosis. In particular, research and data collection should report treatment indication (whether for primary or secondary treatment of respiratory papillomatosis), outcomes related to timing and site of disease recurrence, the need for tracheostomy after the procedure, and longer-term survival. In addition, any effect of the procedure on voice quality should be documented.
- 1.4 Clinicians should enter details for adult patients having the procedure into the ENT UK national audit database.
- 1.5 NICE may review the procedure on publication of further evidence.

## 2 The procedure

### 2.1 Indications and current treatments

- 2.1.1 Respiratory papillomatosis is a condition characterised by benign papillomatous (wart-like) growths in the respiratory tract, which can cause voice changes and airway obstruction. It can affect both children and adults. The condition tends to recur after treatment and is then known as recurrent respiratory papillomatosis.
- 2.1.2 Procedures to remove the papillomas surgically include the use of cold steel dissection, suction diathermy, cryotherapy, carbon dioxide (CO<sub>2</sub>) or other laser ablation, or microdebridement. Any of these may be followed by systemic administration or direct injection of antiviral agents (for example, cidofovir) into the resection sites, with the aim of reducing the frequency of reoperative surgery for recurrent papillomas. Tracheostomy may be needed if significant airway obstruction occurs.

### 2.2 Outline of the procedure

- 2.2.1 Radiofrequency cold ablation involves passing a radiofrequency bipolar electrical current through a medium of normal saline. This produces a plasma field of sodium ions that disrupts intercellular bonds, leading to tissue vaporisation and coagulation. Radiofrequency cold ablation heats tissue to only 60°C to 65°C, which may produce less damage to surrounding structures and postoperative pain than conventional diathermy.
- 2.2.2 The procedure is usually done with the patient under general anaesthesia. Conventional microlaryngoscopy techniques allow introduction of a single-use radiofrequency probe into the lumen of the larynx and trachea.
- 2.2.3 Once the probe tip is in contact with the papilloma, it is activated to produce controlled tissue ablation of individual lesions, together with haemostasis and suction.
- 2.2.4 Steroids and antibiotics may be given after the procedure to reduce inflammation

and the risk of infection, respectively.

## 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 In a case series of 3 adult patients with recurrent papillomas of the nasopharynx, only 1 patient had a recurrent lesion at 4-month follow-up, which was successfully re-excised with endoscopic transnasal radiofrequency cold ablation. A case series of 2 patients reported 'reduced disease recurrence' (no further details provided) in 2 adult patients with juvenile-onset recurrent respiratory papillomatosis who had previously been treated repeatedly by CO<sub>2</sub> laser ablation; 1 was treated by radiofrequency cold ablation treatment alone and 1 by radiofrequency cold ablation together with CO<sub>2</sub> laser ablation. In a case report of 1 paediatric patient with a large de novo laryngeal papilloma treated by radiofrequency cold ablation alone, there was no sign of recurrence at 18-month follow-up.
- 2.3.2 A case series of 6 adult patients with advanced laryngotracheal recurrent respiratory papillomatosis who had received at least 2 years of treatment by CO<sub>2</sub> laser ablation followed by at least 2 years of treatment by radiofrequency cold ablation, reported an increase in the interval between treatments. This was presented as a significant increase (more than 50%) in the interval between treatments in 3 patients when radiofrequency cold ablation was introduced ( $p=0.03$ ) and a modest increase (less than 25%) in the interval between treatments in the other 3 patients ( $p$  value not reported).
- 2.3.3 In another case series of 2 adult patients with extensive and recurrent laryngeal papillomas, 1 patient who presented with severe hoarseness and exertional dyspnoea was found to have a good voice with no exertional dyspnoea at 2-month follow-up (no formal assessment of voice quality reported; no results were presented for the other patient). In the case report of 1 paediatric patient, a dramatic improvement in voice quality was observed (no formal assessment of voice quality reported).

- 2.3.4 The Specialist Advisers listed key efficacy outcomes as reduction in the number or frequency of microlaryngoscopy procedures needed to maintain a safe airway, and achievement of good voice quality.

## 2.4 Safety

- 2.4.1 Minor scarring around the ablated tissues was reported in all patients in a case series of 18 patients (method of assessment of scarring not described).
- 2.4.2 Respiratory papillomas appeared at a new location 4 months after radiofrequency cold ablation in 1 patient in the case series of 18 patients. The procedure was repeated with no further recurrence at 2-month follow-up. The early recurrence raised the possibility of viral seeding (see section 2.4.3).
- 2.4.3 The Specialist Advisers listed theoretical adverse events as laryngeal or airway scarring (with airway stenosis and dysphonia as possible consequences of scarring to the larynx), bleeding and inadequate reduction in the number and size of papillomas, leading to inability to maintain a safe airway. In addition, a Specialist Adviser stated that there is concern about possible seeding of the virus as a result of the procedure.

# 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](#).