

Treating respiratory papillomatosis using electrical energy at low temperature

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This document is about when and how electrical energy at low temperature can be used in the NHS to treat people with respiratory papillomatosis. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This document is written to help people who have been offered this procedure (or in the case of children, their parents or carers) to decide whether to agree (consent) to it or not. It does not describe respiratory papillomatosis or the procedure in detail – a member of your healthcare team should give you full information and advice about these. The document includes some questions you may want to ask your doctor to help you reach a decision.

What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. If a doctor wants to use electrical energy at low temperature to treat respiratory papillomatosis, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the uncertainty surrounding potential risks of the procedure. This should happen before the patient (or their parents or carers) agrees (or doesn't agree) to the procedure. The patient (or their parents or carers) should be given this document and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

NICE is asking doctors to send information about all children and young people who have the procedure and what happens to them afterwards to the Airway Intervention Registry (currently under development) and, about adults, to the [ENT UK national audit database](#) so that the safety of the procedure and/or how well it works can be checked over time.

NICE has encouraged further research into using electrical energy at low temperature to treat respiratory papillomatosis, including details about whether it was the main treatment given or an additional treatment, whether it affected the patient's voice and whether a tracheostomy (an operation to insert a tube into the windpipe to help the person breathe) was needed after the procedure. The research should also record if the condition came back, including how long after the procedure this was, where in the throat or airways this happened, and longer-term survival.

NICE may review the procedure if more evidence becomes available.

This procedure may not be the only possible treatment for respiratory papillomatosis. Your healthcare team should talk to you about whether it is suitable for you (or your child) and about any other treatment options available.

Treating respiratory papillomatosis using electrical energy at low temperature

The medical name for this procedure is 'radiofrequency cold ablation for respiratory papillomatosis'. The word 'ablation' means breaking down or removing.

The procedure is not described in detail here – please talk to your doctor for a full description.

Respiratory papillomatosis is a condition in which non-cancerous wart-like growths called papillomas develop and enlarge in the throat, larynx (voice box) and trachea (main airway). It is caused by infection with the human papillomavirus, and can affect both children and adults. The papillomas can cause hoarseness or a croaky voice, and narrow the airways causing difficulty breathing. Although individual papillomas can be shrunk or removed, the underlying condition may persist and growths tend to come back or develop in new places after treatment.

The main treatment offered is surgery to shrink or remove the growths. The surgical procedures used include removal of the growths by cutting them out with a surgical blade or a laser, or by using other procedures that involve heat or freezing to destroy the growths. Antiviral drugs may also be used to try to stop papillomas coming back or slow down their growth. These are either injected into the area from which the growths have been removed or given as a systemic (affecting the whole body) treatment. If a patient's breathing is badly affected by growths in the airways they may need a tracheostomy (a hole through the neck into the windpipe) so that they can breathe more easily.

Radiofrequency cold ablation aims to dissolve or shrink the papillomas using an electric current. The procedure produces less heat than some other treatments, so that there may be less damage to healthy surrounding tissue and the patient may have less pain afterwards. The

procedure is usually done with the patient under a general anaesthetic. Using a rigid tube with a camera to view the area, the surgeon inserts a probe through the mouth or nose, and down the throat into the areas containing papillomas. When the tip of the probe touches an individual growth, electric current passes into the growth, destroying the tissue. This is repeated for each papilloma. Afterwards, steroids may be given to reduce inflammation, and antibiotics may be given to reduce the risk of infection.

What does this mean for me or my child?

If your doctor has offered you, or your child, treatment with electrical energy at low temperature for respiratory papillomatosis, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this document, and have the opportunity to discuss it with your doctor before making your decision.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your (or your child's) procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I (or my child) might get?
- How good are my (or my child's) chances of getting those benefits? Could having the procedure make me (or my child) feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I (or my child) need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't (or my child doesn't) have the procedure?

You might decide (or decide on behalf of your child) to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 6 studies on this procedure.

How well does the procedure work?

Three studies looked at whether the procedure prevented the condition returning. In one of these studies, a papilloma that returned 4 months after treatment in 1 adult out of 3 who had the procedure was successfully removed when the procedure was repeated. A second study looked at 2 adults with recurring respiratory papillomas since childhood who had previously received carbon dioxide laser treatment many times. One of them had the procedure and carbon dioxide laser treatment, and the other had the procedure on its own. In both patients, the disease came back, but more slowly than before. A third study reported that when the procedure was used to treat a large new papilloma in the throat of a child, the papilloma had not grown back 18 months later.

One study looked at whether treatment was needed less often with the procedure. Six adults with severe recurring papillomas in the throat and airways had 2 years of treatment with carbon dioxide laser followed by 2 years of treatment with the procedure. All the patients needed treatment less often after they started having the procedure.

Two studies reported on voice quality after the procedure. In 1 study of 2 adults with widespread recurring papillomas in the throat, 1 patient who had been very hoarse and had become breathless with exertion before the procedure had good voice quality and was no longer breathless 2 months after the procedure. No information was given about the other patient in that study. In the second study, a child who had the procedure for a growth in their throat experienced a dramatic improvement in voice quality after the procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the aims of the procedure are to reduce the number of treatments needed to keep a patient's airway clear enough for them to breathe safely and to provide good voice quality for patients.

Risks and possible problems

In a study of 18 patients who had the procedure, all 18 had minor scarring in the area from where the growths had been removed. In 1 of these patients new growths appeared in a different area 4 months after the procedure. The procedure was used to treat these new growths and they had not come back 2 months later.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that possible problems include scarring of the throat and airways (which can cause airway narrowing and poor voice quality), and bleeding. They also said that the procedure may not reduce the size or number of growths enough to ensure that patients can breathe safely, and that it may cause the virus to spread.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. HealthTech guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance.

This document is about 'radiofrequency cold ablation for respiratory papillomatosis'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG295

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on accessibility at the bottom of the NICE homepage to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this document in their own information about this procedure.

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