

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Balloon cryoablation for squamous dysplasia of the oesophagus

In squamous dysplasia, the cells lining the gullet (oesophagus) are abnormal. There is a risk that these may become cancerous. In this procedure, a balloon is put into the gullet through a flexible tube with a camera on the end (an endoscope). The balloon is inflated and very cold gas is used to freeze the cells and destroy them (cryoablation).

NICE is looking at balloon cryoablation for squamous dysplasia of the oesophagus.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of specialist advisers, who are consultants with knowledge of the procedure.

This document contains the draft guidance for [consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

**This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.**

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution](#) process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 20 September 2019

Target date for publication of guidance: December 2019

## 1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of balloon cryoablation for squamous dysplasia of the oesophagus is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of [research](#). This could be in the form of randomised controlled trials or published registry data.
- 1.2 Patient selection should be done by clinicians experienced in managing squamous dysplasia of the oesophagus.
- 1.3 Further research should report patient selection, longer term follow-up and complications, including oesophageal stricture.

## 2 The condition, current treatments and procedure

### *The condition*

- 2.1 Squamous cells in the oesophagus may become dysplastic (squamous dysplasia). In some people, this condition may become malignant.

### *Current treatments*

- 2.2 Current management includes lifestyle change, acid-suppressing medicines, endoscopic mucosal resection, endoscopic submucosal dissection, ablative therapies and surgery. Ablative therapies include radiofrequency ablation, photodynamic therapy, argon

plasma coagulation, laser ablation, multipolar electrocoagulation and cryotherapy.

### ***The procedure***

- 2.3 This procedure is usually done under sedation. A balloon catheter is fed through an endoscope, aligned with the dysplastic tissue in the oesophagus, and inflated. Nitrous oxide is then sprayed through a radial diffuser head within the balloon aimed at the target tissue. The tissue is destroyed by the extreme cold. The nitrous oxide gas remains fully contained within the balloon and exits through the proximal end of the catheter.
- 2.4 The ablation sequence is repeated until all the abnormal cells have been destroyed. Multiple ablations can be done without removing the balloon. The procedure typically takes about 15 to 20 minutes to complete.

## **3 Committee considerations**

### ***The evidence***

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 2 sources, which was discussed by the committee. The evidence included 2 case series. It is presented in Table 2b of the [interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: ablation of squamous dysplasia and quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: pain, oesophageal perforation and subsequent oesophageal stricture formation.

***Committee comments***

- 3.4 The committee would encourage the establishment of a registry for this procedure.
- 3.5 The committee noted an incidence of device failure but was informed that the technology is evolving.
- 3.6 The committee was informed that this procedure may lead to less pain than radiofrequency ablation for squamous dysplasia of the oesophagus.

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