

Balloon cryoablation for squamous dysplasia of the oesophagus

Interventional procedures guidance

Published: 28 October 2020

www.nice.org.uk/guidance/ipg683

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 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. Find out what only in research means on the [NICE interventional procedures guidance page](#).
- 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. See [NICE's guideline on Barrett's oesophagus and stage 1 oesophageal adenocarcinoma](#).

The procedure

- 2.3 This procedure is usually done using sedation. A balloon catheter is inserted 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 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 professional experts and the committee considered the key efficacy outcomes to be ablation of squamous dysplasia and quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be pain, oesophageal perforation and subsequent oesophageal stricture formation.
- 3.4 Patient commentary was sought but none was received.

Committee comments

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

ISBN: 978-1-4731-3633-5

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).