

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endoscopic bipolar radiofrequency ablation for malignant biliary obstruction

Cancer of the bile duct or pancreas can block the channels that carry bile and digestive fluids from the gall bladder and pancreas to the small intestine (malignant biliary obstruction). This can cause jaundice, nausea, bloating and abdominal pain. The blockage is usually treated by inserting small tubes called stents, which help to keep the channels open and draining properly. But these stents can also become blocked.

In this procedure, a thin tube with a camera on the end (an endoscope) is passed through the mouth to the blockage. A device is then passed through the endoscope and used to deliver heat energy (radiofrequency) to destroy (ablate) the blockage in the channels. This procedure is done before inserting stents or to clear blocked stents. The aim is to reduce symptoms.

NICE is looking at endoscopic bipolar radiofrequency ablation for malignant biliary obstruction.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts 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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 28 June 2024

Target date for publication of guidance: November 2024

1 Draft recommendations

- 1.1 More research is needed on endoscopic bipolar radiofrequency ablation for treating malignant biliary obstruction.
- 1.2 This procedure should only be done as part of a formal research study, and a research ethics committee needs to have approved its use.

More research

- 1.3 More research is needed on:
- patient selection
 - type, site and stage of tumour
 - quality of life
 - morbidity and mortality
 - complications.

Why the committee made these recommendations

The evidence for this procedure shows that there are no major safety concerns. It also suggests that the procedure can increase how long people live, but the reason for this is unclear. The evidence suggests that the procedure does not improve stent patency (how well and for how long a stent works). Also, there is no evidence on how the procedure affects quality of life, which is a key outcome. There is a lot of variability in the studies on the procedure. For example, they include different tumour types at different locations. They also use different types of stent and varying protocols for radiofrequency ablation. So, there are uncertainties, and more research is needed to better understand the procedure's benefits.

2 The condition, current treatments and procedure

The condition

- 2.1 Biliary obstruction caused by cancers such as cholangiocarcinoma or pancreatic adenocarcinoma can lead to symptoms such as jaundice, nausea, bloating and abdominal pain. Surgical resection is often not possible.

Current treatments

- 2.2 Treatment of unresectable cholangiocarcinoma or pancreatic cancer includes biliary stenting during endoscopic retrograde cholangiopancreatography, chemotherapy, radiation therapy, chemoradiation therapy, immunotherapy and photodynamic therapy. Stents often need to be replaced because of blockage by tumour ingrowth.

The procedure

- 2.3 Endoscopic bipolar radiofrequency ablation (RFA) uses heat energy to ablate malignant tissue that is obstructing the bile or pancreatic ducts. This procedure is usually done before inserting stents (primary RFA), but can also be done to clear obstructed stents (secondary RFA). The aim is to prolong stent patency, so reducing symptoms and improving survival.
- 2.4 The procedure is usually done under sedation. Endoscopic retrograde cholangiopancreatography with fluoroscopic guidance is used to establish the length, diameter and position of the biliary stricture. Under endoscopic visualisation, a bipolar endoscopic RFA catheter is deployed over a guide wire across the stricture. Controlled pulses of radiofrequency energy are applied to ablate the obstructing tumour tissue to allow stent insertion or to clear the lumen of a previously placed stent. Sequential applications are

usually applied throughout the length of the stricture to achieve recanalisation. The treatment can be repeated.

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 7 sources, which was discussed by the committee. The evidence included 5 randomised controlled trials, 1 non-randomised comparative study and 1 systematic review and meta-analysis. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in table 5 of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improvement in quality of life, reduction in biliary obstruction, stent patency, and reduced mortality and morbidity.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: biliary tract perforation, biliary track infection and inflammation, and pain.
- 3.4 One patient organisation submission was received. Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee was informed that this procedure can be done by clinicians who are experienced in endoscopic retrograde cholangiopancreatography.
- 3.6 There is more than 1 device available for this procedure.

- 3.7 The results of some studies suggest that this procedure improves overall survival and reduces mortality, but the reason for this is not well understood. There is also no data on quality of life using a conventional tool.
- 3.8 The effect of this procedure in relieving biliary obstruction may enable chemotherapy to be offered to people who otherwise would not be able to have it. But, its effect on stent patency is uncertain.

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Chair, interventional procedures advisory committee

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