

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endoscopic bipolar radiofrequency ablation for treating biliary obstruction caused by cancer

Cancer of the bile duct or pancreas can block the channels that carry digestive juices from the gall bladder and pancreas to the small intestine. This can cause jaundice, nausea, bloating and abdominal pain. Often it is treated by inserting small tubes called stents, which help to keep the channels open and draining properly. But these stents can themselves become blocked. This procedure uses heat energy both to clear blockage in the channels before inserting stents and to clear blocked stents.

The National Institute for Health and Care Excellence (NICE) is looking at endoscopic bipolar radiofrequency ablation for treating biliary obstruction caused by cancer. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

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

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.

- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations 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: 15 February 2018

Target date for publication of guidance: May 2018

1 Draft recommendations

- 1.1 Current evidence on endoscopic bipolar radiofrequency ablation for treating biliary obstruction caused by cancer shows there are serious but well recognised safety concerns. Evidence on efficacy is limited in quality and quantity. Therefore, this procedure should only be used in the context of research, which should include randomised controlled trials.

- 1.2 Further research should address: patient selection, relief of biliary obstruction, quality of life and survival.

2 The condition, current treatments and procedure

The condition

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

Current treatments

- 2.2 Current management of unresectable cholangiocarcinoma or pancreatic cancer includes biliary stenting during endoscopic retrograde cholangiopancreatography, chemotherapy, biological therapies (for example, monoclonal antibodies), radiation therapy and photodynamic therapy, which involves using a light-sensitive drug and a light source to destroy abnormal cells. Stents often need to be replaced because of blockage by tumour ingrowth.

The procedure

- 2.3 Endoscopic bipolar radiofrequency ablation uses heat energy to ablate malignant tissue that is obstructing the bile or pancreatic ducts. This may be done before inserting stents or to clear obstructed stents.
- 2.4 The procedure is done with the patient under sedation. Endoscopic retrograde cholangiopancreatography with fluoroscopic guidance is

used to establish the length, diameter and position of the stricture. Under endoscopic visualisation, a bipolar endoscopic radiofrequency ablation catheter is deployed over a guide wire across the stricture. Controlled pulses of radiofrequency energy are applied to obstructing tumour tissue to ablate it, and to allow insertion of a stent or clear the lumen of a previously placed stent. Sequential applications are applied throughout the length of the stricture to achieve recanalisation. Repeat treatments may be used if obstruction recurs.

3 Committee considerations

The evidence

- 3.1 To inform the committee, 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 8 sources, which was discussed by the committee. The evidence included 1 systematic review, 4 non-randomised comparative studies (3 of which are also included in the systematic review), and 3 case series (2 of which are also included in the systematic review), and is presented in table 2 of the [interventional procedures overview](#). Other relevant literature is in additional relevant papers in the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: improved quality of life, relief of jaundice, relief of biliary obstruction, reduced stricture and improved survival.

- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding, liver infarction, infection, pancreatitis, cholangitis and biliary leakage.
- 3.4 This guidance is a review of NICE's interventional procedures guidance on [endoscopic bipolar radiofrequency ablation for treating biliary obstruction caused by cholangiocarcinoma or pancreatic adenocarcinoma](#).

Committee comments

- 3.5 Most of the studies described the use of this procedure to treat a stricture followed by stent insertion, but this procedure may also have a role in unblocking existing stents.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

January, 2018

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