



# Endoscopic bipolar radiofrequency ablation for treating biliary obstruction caused by cancer

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www.nice.org.uk/guidance/ipg614

# 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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG464.

### 1 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. Find out <a href="https://www.what.org/white.com/white.c
- 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.
- 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

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 9 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial, 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 the appendix of 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.
- The specialist advisers and the committee considered the key safety outcomes to be: bleeding, liver infarction, infection, pancreatitis, cholangitis and biliary leakage.
- 3.4 Patient commentary was sought but none was received.

#### 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.

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# **Endorsing organisation**

This guidance has been endorsed by Healthcare Improvement Scotland.