NICE National Institute for Health and Care Excellence

NICE guidance

Endoscopic bipolar radiofrequency ablation for malignant biliary obstruction

HealthTech guidance

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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.

Contents

This guidance replaces IPG794 and IPG614.

1 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 suggests that the procedure does not improve stent patency (how well and for how long a stent works), which is the main aim of the procedure. Also, there is a lack of evidence on how the procedure affects quality of life, which is a key outcome. There is conflicting evidence on whether the procedure affects how long people live. In the evidence that shows a small benefit in overall survival, it is unclear why this is happening and whether it is affected by other factors. 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 8 sources, which was discussed by the committee. The evidence included 6 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 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 There are conflicting results on whether the procedure affects overall survival. Randomised controlled trials done in Germany, the Czech republic and South Korea show no effect, while 2 randomised controlled trials done in China show improved overall survival. But the effect seen is small and the reason for it is not

well understood. Also, overall survival could be affected by many factors, such as type, site and stage of tumour, and systemic treatment. There is also a lack of evidence showing that this procedure improves quality of life.

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.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 794 has been migrated to HealthTech guidance 731. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.