Endoscopic bipolar radiofrequency ablation for treating biliary obstruction caused by cholangiocarcinoma or pancreatic adenocarcinoma

Interventional procedures 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. However, 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.

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.

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 Current evidence on the safety and efficacy of endoscopic bipolar radiofrequency ablation for treating biliary obstructions caused by cholangiocarcinoma or pancreatic adenocarcinoma is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Further research, in the form of comparative or observational studies, should document details of patient selection and should report all adverse events. Outcomes should include survival, quality of life, biliary patency and the need for further procedures.

1.3 Clinicians should consider entering patients with pancreatic adenocarcinoma into the EndoHPB 1001 trial.

2 **Indications and current treatments**

2.1 Biliary obstruction due to cholangiocarcinoma and pancreatic adenocarcinoma causes symptoms including jaundice, nausea, bloating and abdominal pain. Surgical resection is often not possible.

2.2 Current management of unresectable cholangiocarcinoma and pancreatic cancer includes biliary stenting done at endoscopic retrograde cholangiopancreatography (ERCP), chemotherapy, biological therapies (for example, monoclonal antibodies), radiation therapy and photodynamic therapy. Stents often need to be replaced because of blockage by tumour ingrowth.

3 **The procedure**

3.1 Endoscopic 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.

3.2 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 delivered by a radiofrequency generator are applied to obstructing tumour tissue to ablate it and to allow insertion of a stent, or to clear the lumen of a previously placed stent. Sequential applications are applied throughout the length of the stricture in order to achieve recanalisation. Repeat treatments may be used if obstruction recurs.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

4.1 A case series of 22 patients reported that deployment of an endoscopic radiofrequency ablation catheter was successful in 95% (21/22) of patients. The 1 unsuccessful deployment occurred because of irretrievable proximal migration of a previously placed plastic stent.

4.2 The case series of 22 patients reported that self-expandable metal stent placement was achieved after endoscopic radiofrequency ablation in 100% (21/21) of successful catheter deployments.

4.3 The case series of 22 patients reported that stent patency was maintained in 95% (20/21) of patients at 30-day follow-up (1 patient developed further biliary obstruction), and 76% (16/21) of patients at 90-day follow-up (2 had died, and 3 developed further biliary obstruction).

4.4 The specialist advisers listed key efficacy outcomes as survival, stent patency, reduced occurrence of cholangitis, reduced need for further biliary intervention and quality of life.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.
5.1 Death within 90 days was reported in 10% (2/21) of patients in a case series of 22 patients. One patient died after biliary decompression by self-expandable metal stent placement could not be achieved and the other patient died as a result of disease progression with a patent stent.

5.2 A hepatic artery pseudoaneurysm, arising from the central right hepatic artery, occurred in 1 patient who underwent endoscopic retrograde cholangiopancreatography (ERCP) with radiofrequency ablation catheter treatment in the right hepatic duct, left hepatic duct and the common hepatic duct biliary confluence. It was unclear if the aneurysm was partially or completely within the liver. Treatment with embolisation successfully stopped the haemorrhage and the patient recovered. This adverse event was reported in the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database.

5.3 Asymptomatic biochemical pancreatitis developed after ERCP in 1 patient in the case series of 22 patients.

5.4 Cholecystitis needing percutaneous gallbladder drainage was reported in 10% (2/21) of patients in the case series of 22 patients. Both patients had tumour encasement of the cystic duct and sepsis before ERCP.

5.5 The specialist advisers listed additional anecdotal events as cholangitis and probe breakage inside the patient, and theoretical adverse events as cholangitis, stent occlusion, damage to surrounding tissues, perforation of bile duct, biliary leak, abscess formation and portal vein thrombosis.

6 Further information

*Information for patients*

NICE has produced information on this procedure for patients and carers ([Information for the public](https://www.nice.org.uk/terms-and-conditions#notice-of-rights)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.
About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.

We have produced a summary of this guidance for patients and carers.

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Endorsing organisation
This guidance has been endorsed by Healthcare Improvement Scotland.