NICE National Institute for Health and Care Excellence

NICE guidance

Selective internal radiation therapy for unresectable primary intrahepatic cholangiocarcinoma

HealthTech guidance

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www.nice.org.uk/guidance/htg489

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 IPG459 and IPG630.

This guidance should be read in conjunction with IPG460 and HTG314.

1 Recommendations

1.1 Current evidence on the safety of selective internal radiation therapy (SIRT) for unresectable primary intrahepatic cholangiocarcinoma shows that there are well-recognised, serious but rare safety concerns. Evidence on its efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research in the form of prospective studies, including randomised controlled trials, should address patient selection, quality-of-life outcomes and overall survival. Patient selection for the research studies should be done by a multidisciplinary team. The procedure should only be done in specialist centres by clinicians trained and experienced in managing cholangiocarcinoma.

1.3 Clinicians should enter details about all patients having SIRT for unresectable primary intrahepatic cholangiocarcinoma onto a suitable registry.

2 The condition, current treatments and procedure

The condition

2.1 Intrahepatic cholangiocarcinoma is a rare type of primary liver cancer originating in the bile ducts within the liver parenchyma. It accounts for about 10% of all cholangiocarcinomas (bile duct cancers).

Current treatments

2.2 Intrahepatic cholangiocarcinoma is not usually diagnosed before the symptoms of biliary obstruction occur, by which time the cancer may be too advanced for curative surgical resection. However, surgical removal with curative intent may occasionally be possible by downstaging the tumour using other types of treatment first. The standard options for palliative treatment include chemotherapy, surgical bypass of the bile duct, or inserting a stent using surgical, endoscopic or percutaneous techniques.

2.3 Selective internal radiation therapy (SIRT; also known as radio-embolisation) can be used as palliative treatment for unresectable primary liver cancer. It may also be used as a neoadjuvant treatment before surgery in patients being considered for curative treatments such as resection or liver transplantation. It aims to deliver radiation directly into the tumour, minimising the risk of radiation damage to surrounding healthy tissue.

The procedure

2.4 SIRT involves delivering microspheres containing radionuclides that emit beta radiation directly into the tumour via the hepatic artery. Under local anaesthesia with fluoroscopic guidance, the radioactive microspheres, which are made of

glass, resin or poly(L-lactic) acid, are injected into branches of the hepatic artery supplying the tumour. Usually, the percutaneous femoral or radial approach is used. The microspheres are designed to lodge in the small arteries surrounding the tumour and release high doses of localised radiation directly into the tumour. The procedure may be repeated depending on the response.

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 11 sources, which was discussed by the committee. The evidence included 3 systematic reviews and meta-analyses and 7 case series (including safety data from 2 conference abstracts), and is presented in table 2 of the interventional procedures overview. It also considered data provided by the selective internal radiation therapy Commissioning through Evaluation registry study. 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: quality of life, survival, downstaging to allow surgical resection and reduction in tumour size.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding, infection, unintended radiation toxicity and hepatic failure.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 There are different types of microspheres used. There are also different types of radionuclides used, but all the evidence considered included studies using yttrium.

3.6 The committee was told that dosimetry in this procedure is complex and needs significant expertise.

3.7 The committee was told that the companies provide comprehensive training for

the procedure.

3.8 The committee did not see any evidence to suggest that there is improved survival in patients in whom the procedure has made subsequent surgical resection possible.

3.9 The committee noted that transient side effects after this procedure are common.

3.10 The committee noted that this procedure has been available since 2002.

3.11 Primary intrahepatic cholangiocarcinoma is a rare condition with a limited life expectancy.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 630 has been migrated to HealthTech guidance 489. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.