NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Selective internal radiation therapy for unresectable primary intrahepatic cholangiocarcinoma

Intrahepatic cholangiocarcinoma is a rare type of liver cancer. It is usually not diagnosed until it is too late to use surgery to remove it (unresectable). Selective internal radiation therapy (known as SIRT) involves injecting tiny radioactive 'beads' into blood vessels that supply blood to the liver, where they become trapped. The beads then release radiation directly into the cancer cells. The aim is to kill the cancer cells while causing as little damage to surrounding healthy tissue as possible.

The National Institute for Health and Care Excellence (NICE) is looking at selective internal radiation therapy for unresectable primary intrahepatic cholangiocarcinoma. 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.

Issue date: [month year]

- 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, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 21 June 2018

Target date for publication of guidance: September 2018

1 Draft 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.

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 primary intrahepatic cholangiocarcinoma onto the UK SIRT register.

2 The condition, current treatments and procedure

The condition

2.1 Cholangiocarcinoma is a rare type of primary liver cancer originating in the bile ducts.

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 such as yttrium-90 or holmium-166 that emit beta or gamma 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 beads are designed to lodge in the small arteries surrounding the tumour and release high doses of localised radiation directly into the liver. 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 10 sources, which was discussed by the committee. The evidence included 3 systematic reviews and meta-

analyses and 6 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 SIRT Commissioning through Evaluation registry. 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 This guidance is a review of NICE's interventional procedures guidance on selective internal radiation therapy for primary cholangiocarcinoma.

Committee comments

3.5 There are different types of microspheres used. There are also different types of radionuclides used, but all the evidence considered by the committee 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 informed 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.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
May, 2018

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