



Selective internal radiation therapy for unresectable colorectal metastases in the liver

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www.nice.org.uk/guidance/ipg672

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 IPG401.

1 Recommendations

- 1.1 Evidence on the safety of selective internal radiation therapy (SIRT) for unresectable colorectal metastases in the liver shows there can be serious complications, but these are well recognised and infrequent.
 - In people who cannot tolerate chemotherapy or have liver metastases that are
 refractory to chemotherapy, there is evidence of efficacy but this is limited,
 particularly for important outcomes such as quality of life. Therefore, in these
 people, this procedure should only be used with special arrangements for
 clinical governance, consent, and audit or research. Find out what special-arrangements-mean on the NICE interventional procedures guidance page.
 - In people who can have chemotherapy, evidence on overall survival and quality
 of life is inadequate in quality. Therefore, in these people, 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 Clinicians wishing to do SIRT for unresectable colorectal metastases in the liver, in people who cannot have chemotherapy or have liver metastases that are refractory to chemotherapy, should:
 - Inform the clinical governance leads in their NHS trusts.

- Give patients clear written information to support <u>shared decision making</u>, including NICE's information for the public.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure.
 Clinicians should enter details for all patients having SIRT for unresectable colorectal metastases in the liver onto a suitable register.
- Patient selection should be done by a specialist hepatobiliary cancer multidisciplinary team that can offer the full range of treatment options for this condition.
- 1.4 This procedure should only be done by clinicians with specific training in SIRT including techniques to minimise the risk of damage to surrounding tissue.
- Further research should report details of patient selection, whether the primary colorectal tumour arose in the left or right side of the colon, extrahepatic disease, and tumour-to-liver volume. Outcomes should include survival and quality of life.
- 1.6 NICE may update the guidance on publication of further evidence.

2 The condition, current treatments and procedure

The condition

Around 30% to 50% of people with colorectal cancer have liver metastases at the time of presentation or develop them during the course of the disease.

Current treatments

2.2 Treatment of liver (hepatic) metastases depends on their extent and

location. For unresectable tumours, treatment options include thermal ablation techniques, chemotherapy, different types of arterial embolisation therapy and external beam radiotherapy.

The procedure

- 2.3 Selective internal radiation therapy (SIRT; also known as radioembolisation) can be used as palliative treatment for unresectable colorectal metastases in the liver.
- 2.4 SIRT involves delivering microspheres containing radionuclides that emit beta radiation directly into the tumour. This aims to minimise the risk of radiation damage to surrounding healthy tissue. Using local anaesthesia and fluoroscopic guidance, the radioactive microspheres are injected into branches of the hepatic artery supplying the tumour. A percutaneous approach is used through the femoral or radial artery. The microspheres lodge in small arteries within and surrounding the tumour, releasing high doses of radiation directly into it. The procedure may be repeated depending on the response.

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 3 publications from 4 randomised controlled trials (3 were analysed together in a single report and 2 of these 3 were also used for a post-hoc analysis, reported in a single study), 2 non-randomised comparative studies and 3 case series. It 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: quality of life, survival and reduction in tumour volume.

- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: hepatic toxicity, abdominal pain and haematological toxicity.
- Patient commentary was sought but none was received.

Committee comments

- The committee was advised that the benefit is greater for patients with limited extrahepatic disease and tumour-to-liver volumes below 25%.
- There are different types of microspheres used. There are also different types of radionuclides used, but the evidence discussed by the committee only included studies using yttrium.
- 3.7 The committee was told that dosimetry in this procedure is complex and needs significant expertise.
- 3.8 The committee noted that many studies did not report quality of life and it considers this to be an important outcome.
- 3.9 The committee noted that adverse events may be attributable to selective internal radiation therapy, chemotherapy, or both.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.